

# United States Senate

WASHINGTON, DC 20510

November 1, 2016

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

Dear Ms. Bresch,

Thank you for your September 12, 2016, response to our letter on Mylan's repeated and significant price increases for the EpiPen Auto-Injector (EpiPen).<sup>1</sup> While your response—and other information that has been made public since our letter was sent—provides important context about Mylan's pricing decisions for the EpiPen, it also leaves critical questions unanswered and raises new questions.

We agree with your assertion that “the [EpiPen] pricing puzzle that frustrates [us] and [our] constituents...transcends this product and our company.” We share your desire to “address the underlying issues that lead to these pricing controversies” across the U.S. health care system—not just at Mylan.<sup>2</sup>

The information you provided in response to our request provides a number of important insights about Mylan and EpiPen pricing; however, we remain frustrated with both the lack of information and lack of clarity in your response, and your insistence that you are not aware of the basic facts about sales of your own drug to Medicaid and Medicare Part D recipients. Your September 12, 2016, letter gave us a seemingly straightforward set of a few basic facts about the EpiPen: each EpiPen 2-Pak has a \$608 wholesale acquisition cost (WAC), \$274 of which Mylan receives after fees and rebates; after taking out the cost of goods and “additional expenses,” Mylan receives a \$50 profit per pen.<sup>3</sup> In late September, however, you admitted that your calculations included an *undisclosed* 37.5% tax rate—which reduced your reported profits by 60%.<sup>4</sup> Furthermore, you recently released an EpiPen profitability analysis using different metrics

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<sup>1</sup> Letter from Mylan (transmitted through Stephen M. Ryan et al., McDermott, Will & Emery LLP) to Senators Warren, Leahy, Boxer, Durbin, Reed, Sanders, Brown, Klobuchar, Whitehouse, Tester, Udall, Franken, Blumenthal, Schatz, Baldwin, Donnelly, Murphy, Hirono, Heitkamp, and Markey, September 12, 2016. Hereafter referred to as “Mylan Response, September 12, 2016”.

<sup>2</sup> Mylan Response, September 12, 2016, p. 3.

<sup>3</sup> Mylan Response, September 12, 2016, p. 2; U.S. House Committee on Oversight and Government Reform, *Reviewing the Rising Price of EpiPens* (Hearing) (September 21, 2016) (online at <https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/>).

<sup>4</sup> Not only was this 37.5% tax rate not disclosed in your original numbers—it has, as one analyst put it, “nothing to do with reality.” In 2015, Mylan's overall tax rate was only 7.4%; in the U.S. the company had a *negative* effective tax rate. See Mark Maremont, “Mylan's EpiPen Profit 60% Higher Than Told to Congress,” *Wall Street Journal*

per pen than the metrics used in your response to us, making direct comparisons challenging.<sup>5</sup> Additional reports from third parties, including the Center for Medicare and Medicaid Services, have also provided new information, further complicating the set of data available for review.<sup>6</sup>

Our analysis of available information from you and others clarifies that:

- (1) Mylan's My EpiPen Savings Card and Patient Assistance Program do not help the vast majority of EpiPen users. The free product provided through the Patient Assistance Program represents less than 1% of all EpiPens sold<sup>7</sup>; the Savings Cards are used to reduce copays or premiums on less than 25% of purchases.<sup>8</sup>
- (2) The majority of EpiPen's cost increases appear to have been borne by taxpayers, via higher costs for programs like Medicare and Medicaid, and by employers and insured patients, via higher premiums.<sup>9</sup>
- (3) Mylan's pricing system is complex and non-transparent, allowing the company to segregate consumers into categories: the uninsured, Medicaid patients, Medicare patients, and the commercially insured. This segmentation allows Mylan to charge different prices to each category of patient, shielding some customers from price increases while shifting costs to others. Mylan maximizes revenue for each patient segment, ensuring high profits.

While the information you provided to us gives important insights into how and why Mylan establishes EpiPen prices, your answers raise additional questions. Moreover, your company did not answer all of our initial questions. We are therefore writing today to request additional information.

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(September 26, 2016) (online at <http://www.wsj.com/articles/mylan-clarifies-epipen-profit-figures-it-provided-to-congress-last-week-1474902801>).

<sup>5</sup> Mylan Form 8-K, September 26, 2016 (online at <http://apps.shareholder.com/sec/viewerContent.aspx?companyid=ABEA-2LQZGT&docid=11606369>).

<sup>6</sup> See Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at <https://consumermediallc.files.wordpress.com/2016/10/wyden-epipen-medicaid-letter-from-cms-10-5-16.pdf>).

<sup>7</sup> According to Mylan's Response, the company provided 3,042 2-Paks (6,084 individual devices) through its Patient Assistance Program from September 2015 to September 2016. From September 5, 2015 through September 2, 2016, Mylan sold a total of 3,851,294 prescriptions, or 7,702,588 total pens. Therefore, pens provided through the Patient Assistance Program represent 0.079% of total sales. See Mylan Response, September 12, 2016, p. 6; p. 4.

<sup>8</sup> According to Mylan's Response, the My EpiPen Savings Card was used to fill 856,186 prescriptions (for 1,712,372 individual devices). Mylan sold 2,995,108 prescriptions without the use of a Savings Card, for a total of 3,851,294 total prescriptions, or 7,702,588 total pens. Therefore, Mylan's MyEpiPen Savings Cards are used for 22.23% of total sales. See Mylan Response, September 12, 2016, p. 4.

<sup>9</sup> See, for example, Juliette Cubanski, Tricia Neuman, and Anthony Damico, "How Much Has Medicare Spent on the EpiPen Since 2007," *Kaiser Family Foundation* (September 2016) (online at <http://kff.org/medicare/issue-brief/how-much-has-medicare-spent-on-the-epipen-since-2007/>).

## **Mylan's Price Discrimination and Its Impact on Consumers, Taxpayers, and Insurance Premiums**

Your response to our letter and additional information provided to Congress and the public include key insights into drug industry pricing strategies, including the fact that, unlike many other industries, the drug industry uses a pricing benchmark—Wholesale Acquisition Cost (WAC)—that does not reflect what any of its customers or third party-payers actually pay for the product.

In fact, your response reveals that there is a significant gap between the listed WAC for EpiPen and what consumers actually pay. According to your response, “[t]he [WAC] price of EpiPen Auto-Injectors does not reflect what Mylan is paid.”<sup>10</sup> Documents made public by the House Oversight Committee reveal that Mylan has increased the WAC of an EpiPen 2-Pak from \$99 in 2008 to \$608 in 2016—a total increase of \$509. But your company also reported that the average revenue that Mylan receives per 2-Pak, meanwhile, increased by only \$175, from \$87 in 2008 to \$274 in 2016.<sup>11</sup>

Though Mylan does not retain the entire increase in WAC, it has profited handsomely from EpiPen sales: according to Mylan's recent SEC filings, the EpiPen's net product profitability increased from \$3 million in 2008 to \$419 million in 2016.<sup>12</sup> Ultimately, it is the manipulation of the WAC that allows Mylan to maximize its revenue: Mylan charges significantly different prices to different customers. Mylan appears to be engaging in practices that shield some consumers from price increases and high deductibles while shifting these costs—both directly and indirectly—to others. The net result of this process is profitable for Mylan—but these increased revenues come at a significant cost to consumers and taxpayers.

We are particularly interested in and seek additional information on Mylan's pricing and pricing strategies for four different groups of customers.

**1. The Uninsured:** Absent additional assistance, this group would be faced with the highest costs from Mylan's price increases. However, information you provided reveals that they represent only a small portion of Mylan's market. To insulate these consumers from cost increases, Mylan has instituted its Patient Assistance Program. In response to criticism of its recent price increases, Mylan recently expanded eligibility for the program—a step you claimed was “unprecedented” and would “ensure that everyone needs an EpiPen Auto Injector is able to get one.”<sup>13</sup> But prior to the recent expansion of the eligibility requirements, this program appeared to help only a miniscule number of patients who purchase the EpiPen; according to information provided in response to our request, from September 2015 to September 2016, you

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<sup>10</sup> Mylan Response, September 12, 2016, p. 2.

<sup>11</sup> See Mylan, “Wholesale Acquisition Cost (WAC) Versus Average Net Price to Mylan (2008-2016E) (per 2-Pak),” Document provided to the House Oversight and Government Reform Committee (September 2016).

<sup>12</sup> Mylan Form 8-K, September 26, 2016 (online at <http://apps.shareholder.com/sec/viewerContent.aspx?companyId=ABEA-2LQZGT&docid=11606369>).

<sup>13</sup> Mylan Response, September 12, 2016, p. 3.

provided only 3,042 EpiPen 2-Paks to consumers via the Patient Assistance Program—representing roughly 0.08% of total sales.<sup>14</sup>

**2. Medicaid Patients.** Medicaid patients either receive free prescription drugs or pay a small, fixed copay for their products. As a result, the patients are insulated from Mylan’s cost increases. Taxpayers, however, are not. When Medicaid patients use EpiPen, taxpayers reimburse pharmacists for their products. These reimbursements vary by state, but they are generally based upon the list price of the drug—the WAC, or a similar measure like Average Wholesale Price (AWP).<sup>15</sup> As a result, taxpayers are faced with the significant burden of Mylan’s rapid price increases. Recently released information reveals that Mylan acted to maximize taxpayer costs by incorrectly labeling the EpiPen as a generic drug since 1997. According to the Center for Medicare and Medicaid Services (CMS), this incorrect label has allowed the company to artificially “reduce the amount of quarterly rebates Mylan owes [the government] for EpiPen,” further pushing the burden of price increases onto taxpayers.<sup>16</sup> On October 7, 2016, Mylan announced a \$465 million settlement with the Department of Justice (DOJ) over this issue—an insubstantial fine that is likely less than Mylan saved by misclassifying the EpiPen.<sup>17</sup> Our initial request sought information on the volume of EpiPen’s sales to Medicaid patients. This is critical business information for company executives, and information that Mylan is required to obtain in order to pay the correct Medicaid rebates. And after we sent our letter, this information became publicly available, with the Kaiser Family Foundation estimating that Medicaid recipients used 700,000 EpiPen prescriptions in 2014.<sup>18</sup> But in response to our initial request, and again in October 2016, you indicated that the company was unable to provide this information.

**3. Medicare Patients.** Medicare patients receive their coverage for the EpiPen via the Medicare Part D program. Four in ten of these patients (39%) are low-income subsidy (LIS) patients, and pay small, flat co-pays for their drugs; they have been and will be entirely insulated from your price increases, with taxpayers instead picking up the costs. The remaining 61% of Part D recipients receive the standard Part D benefits, meaning they will pay higher premiums, deductibles, and co-payments to access their drugs. In 2014, Medicare Part D enrollees paid an average out-of-pocket co-payment of \$56 per EpiPen prescription—representing about 20% of

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<sup>14</sup> According to Mylan’s Response, the company provided 3,042 2-Paks (6,084 individual devices) through its Patient Assistance Program from September 2015 to September 2016. From September 5, 2015 through September 2, 2016, Mylan sold a total of 3,851,294 prescriptions, or 7,702,588 total pens. Therefore, pens provided through the Patient Assistance Program represent 0.079% of total sales. See Mylan Response, September 12, 2016, p. 6; p. 4.

<sup>15</sup> See Medicaid, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, Quarter Ending June 2016* (2016) (online at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf>).

<sup>16</sup> Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at <https://consumermediallc.files.wordpress.com/2016/10/wyden-epipen-medicaid-letter-from-cms-10-5-16.pdf>), p. 2.

<sup>17</sup> Mylan, “Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector (press release)” (October 7, 2016) (online at <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector>).

<sup>18</sup> Kaiser Family Foundation, “Spending and Utilization of EpiPen within Medicaid,” *Kaiser Family Foundation* (October 7, 2016) (online at <http://kff.org/medicaid/issue-brief/spending-and-utilization-of-epipen-within-medicaid/>).

the cost of the drug to Medicare Part D.<sup>19</sup> The remaining 80% of the costs—and the cost increases—were paid for by the Part D plans themselves. These costs are ultimately reflected in higher premiums and higher taxpayer costs. While the Part D plans are able to negotiate with Mylan for lower prices on EpiPens, you failed to respond to our request for information on the extent of the discounts your company provides to Part D plans on behalf of enrollees. Our initial request sought information on the volume of EpiPen’s sales to Medicare Part D patients. Like Medicaid utilization data, this is critical business information for company executives and shareholders. And, like the Medicaid utilization information, after we sent our initial letter this information became publicly available, with the Kaiser Family Foundation estimating that approximately 211,000 Medicare Part D recipients used EpiPen prescriptions in 2014.<sup>20</sup> But in response to our initial request, and again in October 2016, you indicated that the company was unable to provide this information.

**4. Patients with Employer or Affordable Care Act Insurance Coverage.** These patients represent the vast majority of EpiPen users, and have coverage structured in a similar way: they pay a co-pay or face deductibles for the drug, which can often result in their being charged hundreds of dollars—or even the full WAC price for EpiPen. To address the concerns raised by these high costs, Mylan offers the My EpiPen Savings Card, which (after changes made this summer) covers up to \$300 of out-of-pocket costs. When used, these cards can help cover copays and deductibles. According to information you provided to us, 75% of Savings Card users had \$0 copay. For the remaining 25%, however, the average co-pay was significantly higher—\$207.<sup>21</sup> Unfortunately, the information you provided to us reveals that the vast majority of total EpiPen prescriptions—78% —were filled by patients who did not use the Savings Card.<sup>22</sup> There are two reasons for this. The approximately one million EpiPen prescriptions filled by Medicare and Medicaid are not even eligible for the Savings Card program. But this leaves approximately two million customers who used employer or Affordable Care Act coverage (and were therefore eligible to use the Savings Card) who received EpiPen prescriptions but did not use the card. This means that over 70% of eligible consumers with employer or ACA insurance did not use the card.

These facts raise several questions about significant gaps in the effectiveness of your Savings Card program. Moreover, the cost increases for the drug that are not covered by either the Savings Card or by patients are covered by insurers and are ultimately passed on as increased

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<sup>19</sup> See Juliette Cubanski, Tricia Neuman, and Anthony Damico, “How Much Has Medicare Spent on the EpiPen Since 2007,” *Kaiser Family Foundation* (September 2016) (online at <http://kff.org/medicare/issue-brief/how-much-has-medicare-spent-on-the-epipen-since-2007/>). The average out-of-pocket spending by non-LIS enrollees in 2014, per EpiPen prescription, was \$56; the average total Medicare Part D spending per prescription was \$344. Thus, the enrollee co-payment represents 16.2% of Medicare Part D’s spending per prescription.

<sup>20</sup> Juliette Cubanski, Tricia Neuman, and Anthony Damico, “How Much Has Medicare Spent on the EpiPen Since 2007,” *Kaiser Family Foundation* (September 2016) (online at <http://kff.org/medicare/issue-brief/how-much-has-medicare-spent-on-the-epipen-since-2007/>).

<sup>21</sup> Mylan Response, September 12, 2016, p. 4.

<sup>22</sup> According to Mylan’s Response, the My EpiPen Savings Card was used to fill 856,186 prescriptions (for 1,712,372 individual devices). Mylan sold 2,995,108 prescriptions without the use of a Savings Card, for a total of 3,851,294 total prescriptions, or 7,702,588 total pens. Therefore, Mylan’s MyEpiPen Savings Cards are used for 22.23% of total sales. 77.77% of EpiPen prescriptions were filled without the Savings Card. See Mylan Response, September 12, 2016, p. 4.

premiums. While the insurance plans—either directly or through Pharmacy Benefit Managers (PBMs)—are able to negotiate with Mylan for lower prices on EpiPen, you failed to respond to our request for information on the extent of the discounts your company provides.

### Additional Questions

To further enhance our understanding of your decision to increase the price of EpiPens, please provide answers to the following questions no later than November 14, 2016.

1. A recent analysis of Medicare Part D spending from the Kaiser Family Foundation found that Medicare Part D spending on EpiPens increased from \$7 million in 2007 to \$87.9 million in 2014—a 1,151% increase. Total Medicare Part D enrollee out-of-pocket EpiPen spending doubled during the same time period.<sup>23</sup> In 2015, Medicare Part D spending on EpiPens increased yet again to \$121.7 million.<sup>24</sup>

One reason for this dramatic increase is Medicare’s lack of bargaining power. The Department of Health and Human Services (HHS) and the Medicare program are legally barred from negotiating directly with manufacturers for lower drug prices. Instead, Medicare Part D plan providers negotiate with manufacturers for rebates, which are typically lower than those negotiated by commercial insurers. Accounting for rebates, Kaiser estimates that Part D spending increased by 1,100% between 2007 and 2014.<sup>25</sup>

- a. What is the average rebate (per EpiPen two-pack) that Mylan offered to insurers (including rebates to PBMs negotiating on behalf of those insurers) for EpiPen sold to Medicare part D enrollees each year from 2007 to 2016? What was the annual average pre-tax revenue per prescription Mylan received after taking these rebates into account?
- b. What is the range of rebates offered to insurers (including PBMs negotiating on behalf of those insurers) for EpiPen sold via the Part D program each year from 2007-2016?
- c. How many EpiPen prescriptions did Medicare Part D enrollees fill each year from 2007-2016?

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<sup>23</sup> Juliette Cubanski, Tricia Neuman, and Anthony Damico, “How Much Has Medicare Spent on the EpiPen Since 2007,” *Kaiser Family Foundation* (September 2016) (online at <http://kff.org/medicare/issue-brief/how-much-has-medicare-spent-on-the-epipen-since-2007/>).

<sup>24</sup> Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at <https://consumermediallc.files.wordpress.com/2016/10/wyden-epipen-medicaid-letter-from-cms-10-5-16.pdf>), p. 1.

<sup>25</sup> *Id.*

2. Mylan provides Saving Cards for patients who have insurance coverage through either an employer or through an Affordable Care Act (ACA) exchange. Any costs for EpiPen not covered through these Savings Cards are paid either directly by patients or by insurers.
  - a. What is the average rebate (per EpiPen two-pack) that Mylan offered to insurers (including rebates to PBMs negotiating on behalf of those insurers) for EpiPen sold to those covered by employer or ACA coverage each year from 2007 to 2016? What was the annual average pre-tax revenue per prescription Mylan received after taking these rebates into account?
  - b. What is the range of rebates offered to insurers (including PBMs negotiating on behalf of those insurers) for EpiPen sold to those covered by employer or ACA coverage each year from 2007 to 2016?
  - c. How many EpiPen prescriptions did patients covered by employer or ACA coverage fill each year from 2007 to 2016?<sup>26</sup>
  - d. Individuals with private insurance coverage or Affordable Care Act coverage are eligible to use the Savings Card. But information you provided, along with additional utilization information obtained by our staff, indicate that approximately 70% of these individuals did not use the Savings Card. How has the company sought to guarantee that all eligible consumers are aware of and able to use the Savings Card?
3. Most Medicaid recipients pay a flat fee for prescriptions, with the remainder of the costs paid by federal and state governments.
  - a. How many EpiPen prescriptions were filled through the Medicaid program each year from 2007-2016?
  - b. What was the average rebate per prescription that Mylan provided to the Medicaid program each year from 2007-2016?
  - c. Did Mylan provide supplemental rebates to any state Medicaid programs? If so, what was the range (per prescription) of these rebates?

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<sup>26</sup> In the event you are unable to provide separate information for Part D and employer/ACA plans as requested in questions 1(a-c) and 2(a-c), please provide the following information (a) What is the average rebate (per EpiPen two-pack) that Mylan offered to all non-Medicaid insurers (including rebates to PBMs negotiating on behalf of those insurers) for EpiPen sold to the individuals covered by these insurers each year from 2007 to 2016? What was the average revenue per prescription received by Mylan after taking these rebates into account? (b) What is the range of rebates offered to non-Medicaid insurers (including PBMs negotiating on behalf of those insurers) for EpiPen each year from 2007-2016? (c) How many EpiPen prescriptions did non-Medicaid insurance enrollees fill each year from 2007-2016?

4. According to information released by the Center for Medicare and Medicaid Services (CMS), the EpiPen has been classified as a generic drug within the Medicaid program since 1997. CMS has made clear that “EpiPen does not meet the definition of a multi-source [generic] drug, but, in fact meets the definition of a single source or brand drug.” On “multiple occasions” since 1997, CMS has “expressly told Mylan that the product is incorrectly classified.” The incorrect classification of the EpiPen has been a financial boon for Mylan: it “reduces the amount of quarterly rebates Mylan owes for EpiPen,” thus maximizing Mylan’s Medicaid revenue at the expense of taxpayers.<sup>27</sup>

In spite of direct requests that it do so, Mylan refused to re-classify the EpiPen as a brand drug. On October 7<sup>th</sup>, Mylan announced a \$465 million settlement with DOJ as punishment for its misclassification. However, this settlement does not force Mylan to admit to wrongdoing and assesses a fine that is likely *less* than the amount Mylan has withheld from Medicaid as a result of the misclassification.<sup>28</sup>

- a. Please provide copies of all guidance that Mylan received directly from CMS, since 2007, informing the company that the EpiPen was misclassified. In addition, please provide any guidance that CMS issued, either directly to Mylan or to the drug industry at large, indicating that the EpiPen was misclassified.
- b. Please describe any actions that Mylan took, after receiving CMS guidance, to review the classification of the EpiPen. How did Mylan justify maintaining the EpiPen’s classification as a generic drug?
- c. The Medicaid Drug Rebate Program is designed to protect taxpayers from the high cost of outpatient prescription drugs. Under the Rebate Program, drug manufacturers provide Medicaid with rebates in exchange for state Medicaid coverage of their drugs, insulating Medicaid—and taxpayers—from high drug list prices.<sup>29</sup> Because branded drugs are more expensive than generics, the program requires the manufacturers of branded drugs to pay higher rebates than manufacturers of generic drugs: manufacturers of brand drugs pay Medicaid pay a minimum 23% rebate, based on the drug’s average manufacturer price (AMP), and contains additional protections so that manufacturers refund taxpayers the difference if a brand-name drug's price rises at a pace that exceed the inflation rate.<sup>30</sup> The rebate for generic products, meanwhile, is only 13 percent of the

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<sup>27</sup> Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at <https://consumermediallc.files.wordpress.com/2016/10/wyden-epipen-medicaid-letter-from-cms-10-5-16.pdf>), pg. 2.

<sup>28</sup> Mylan, “Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector (press release)” (October 7, 2016) (online at <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector>).

<sup>29</sup> Medicaid.gov, “Medicaid Drug Rebate Program” (online at <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>).

<sup>30</sup> Social Security Act § 1927(c)(1)(B). The law requires that brand name drug manufacturers pay a rebate equal to the higher of either a) 23.1% of the drug cost plus the inflation rebate, or b) the difference between the average drug

AMP.<sup>31</sup> For all years after 2007 that Mylan classified EpiPen as a generic drug in the Medicaid program, please provide:

- i. The total rebate that Mylan paid Medicaid for EpiPens, and
  - ii. The estimated rebate that Mylan *would* have paid Medicaid for EpiPens if EpiPen had been classified as a branded drug, assuming a rebate valued at 23% of the EpiPen's AMP.
5. Your response offered a general breakdown of the EpiPen 2-Pak's WAC: "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...[A]dditional 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."<sup>32</sup> At a September 21, 2016 hearing, you provided similar estimates to members of the House Oversight and Government Reform Committee.<sup>33</sup> These estimates reflect all EpiPen sales, including sales to the uninsured, to Medicaid patients, and to those with Medicare Part D, employer, or ACA coverage.
- a. Please provide a description of *all* deductions you used to arrive at a \$50-per-pen profit from a starting WAC of \$608, including the 37.5% tax rate you left out of your original response. How do you justify using a 37.5% tax rate? At what point(s) in your calculation did you apply the 37.5% tax rate? Why did you not inform Congress from the outset about the 37.5% tax rate included within your calculations?
  - b. It is unclear how Mylan determined that it receives \$274, on average, in revenue per EpiPen 2-Pak. You told the House Oversight Committee that the \$334 difference between the WAC and Mylan's revenue can be explained by "the middlemen in the system, so that's either the pharmacy benefit managers, retailers, wholesalers, [and] insurers," but stated that you did not "specifically know the breakdown between those four buckets."<sup>34</sup>

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cost and "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States."

<sup>31</sup> Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at <https://consumermediallc.files.wordpress.com/2016/10/wyden-epipen-medicaid-letter-from-cms-10-5-16.pdf>), pg. 2.

<sup>32</sup> Mylan Response, September 12, 2016, pg. 2.

<sup>33</sup> House Committee on Oversight and Government Reform, *Reviewing the Rising Price of EpiPens* (hearing), 114<sup>th</sup> Congress (September 21, 2016) (online at <https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/>).

<sup>34</sup> CQ Congressional Transcripts, "House Oversight and Government Reform Committee Holds Hearing on EpiPens (Final Transcript)" (September 21, 2016), p. 119, 94.

Using Mylan's figures, a Deutsche Bank analysis suggests that Mylan likely offers pharmacy benefit managers (PBMs) a 48.9% average rebate.<sup>35</sup> But the Pharmaceutical Care Management Association (PCMA)—a national trade organization for PBMs—has suggested that a 33% rebate is more realistic—which would push Mylan's average revenue above \$274 per 2-Pak.<sup>36</sup>

To help us better understand how Mylan arrived at an average of \$274 in revenue, please provide:

- i. A description of how your inclusion of a 37.5% tax rate affected your calculation of average revenue.
    - ii. The average rebate that Mylan offers PBMs for Epi-Pen 2-Paks and for Epi-Pen Jr. 2-Paks.
    - iii. A breakdown of how the \$334 difference is allocated between PBMs, wholesalers, and retailers.
  - c. Please provide a detailed breakdown of the \$69 cost of goods. How much of the cost of goods is spent on drug ingredients versus device materials?
  - d. Mylan purportedly spends \$105, per EpiPen 2-Pak, on “research and development, sales, marketing, regulatory compliance, distribution, various access programs, and acquisition costs.”<sup>37</sup>
    - i. Please provide a detailed breakdown of how the \$105 is allocated between each of the eight categories. Within the “access programs” category, please break down the cost by specific access program.
6. You recently touted Mylan's “unprecedented” decision to introduce a generic version of the EpiPen, at a WAC of \$300.<sup>38</sup>
- a. Mylan anticipates receiving \$200 in revenue per two generic EpiPens.<sup>39</sup> Please provide a description of how Mylan reached the \$200 figure. Disclose *all* deductions that you use to calculate any difference between the WAC and your average revenue, and explain any differences in deductions used for the brand-name product and the forthcoming generic

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<sup>35</sup> Deutsche Bank Markets Research, “Airing Their Dirty Laundry: Will PBMs See Increased Scrutiny in DC?” (September 15, 2016), p. 3.

<sup>36</sup> Pharmacy Care Management Association, “The Facts on EpiPen Costs” (online at <http://www.pcmnet.org/images/stories/uploads/2016/the%20facts%20on%20epipen%20costs%20-%20infographic.pdf>).

<sup>37</sup> Mylan Response, September 12, 2016, pg. 2.

<sup>38</sup> Heather Bresch, *Testimony of Mylan CEO Heather Bresch before the United States House of Representatives Committee on Oversight and Government Reform* (September 21, 2016) (online at <https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf>), p. 3.

<sup>39</sup> CQ Congressional Transcripts, “House Oversight and Government Reform Committee Holds Hearing on EpiPens (Final Transcript)” (September 21, 2016), p. 119, 94.

- b. How much profit will Mylan make per generic EpiPen?
  - c. You recently announced that Mylan is “creating a direct ship option” for its generic EpiPens, “allowing patients to purchase the generic product directly from Mylan for \$300.”<sup>40</sup> This “direct ship” option will allow Mylan to reap the full \$300 WAC price from consumers. How many customers does Mylan anticipate will use the “direct ship” option? How does Mylan plan on advertising the “direct ship” option to consumers? Will Mylan educate consumers about purchasing options that result in lower consumer out-of-pocket costs?
7. Mylan estimates that “as many as 8 million Americans” have food allergies that could trigger life-threatening anaphylactic shock.<sup>41</sup> From September 2015 through September 2016, however, your Patient Assistance Program provided only 3,042 EpiPen 2-Paks to only 2,965 customers.<sup>42</sup> It defies logic that of the 8 million Americans that need EpiPens, only 3,000 meet the Eligibility requirements for the Patient Assistance Program.<sup>43</sup> You recently doubled the eligibility threshold for the program to those at or below 400% of the federal poverty line.<sup>44</sup> While expanding the program may look good on paper, it is not a meaningful step forward if only a couple thousand people utilize the program each year. What steps will Mylan take to increase utilization of its Patient Assistance Program?
  8. You recently announced multiple expansions to your patient accessibility programs. However, your accessibility programs do not address the needs of first responders—many of whom are struggling to pay for EpiPens.<sup>45</sup> While the introduction of a \$300 generic may help reduce the burden for some first responders, \$300 may still pose a significant burden. How does Mylan plan on ensuring that first responders across the country have access to EpiPens?

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<sup>40</sup> Heather Bresch, *Testimony of Mylan CEO Heather Bresch before the United States House of Representatives Committee on Oversight and Government Reform* (September 21, 2016) (online at <https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf>), p. 3.

EpiPen.com, “Food allergy prevalence” (online at <https://www.epipen.com/what-is-anaphylaxis/what-causes-anaphylaxis/food-allergies>).

<sup>42</sup> Mylan Response, September 12, 2016, pg. 6.

<sup>43</sup> As of the first quarter of 2016, 8.6% of Americans were uninsured. See *Obamacare Facts*, “ObamaCare: Uninsured Rates” (online at <http://obamacarefacts.com/uninsured-rates/>). If we assume that the need for EpiPens is equal between insured and uninsured Americans, then roughly 688,000 of the 8 million Americans with food allergies are likely to be uninsured.

<sup>44</sup> Mylan Response, September 12, 2016, pg. 3; 5.

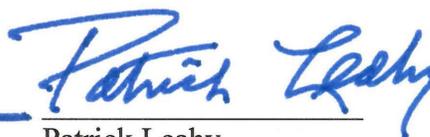
<sup>45</sup> Ike Swetlitz, “High price of EpiPens spurs consumers, EMTs to resort to syringes for allergic reactions,” *STAT* (July 6, 2016) (online at <https://www.statnews.com/2016/07/06/epipen-prices-allergies/>).

Thank you in advance for your prompt, clear, and accurate responses to these questions. We look forward to continuing to work with you to ensure that all Americans have access to life-saving medication.

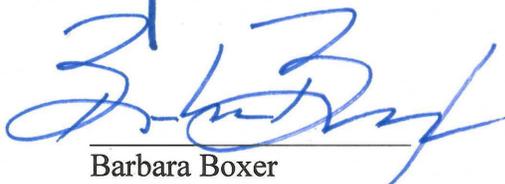
Sincerely,



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



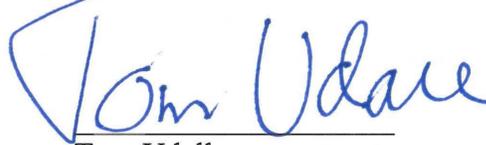
Sherrod Brown  
United States Senator



Amy Klobuchar  
United States Senator



Sheldon Whitehouse  
United States Senator



Tom Udall  
United States Senator

*Kirsten Gillibrand*

Kirsten Gillibrand  
United States Senator

*Al Franken*

Al Franken  
United States Senator

*Richard Blumenthal*

Richard Blumenthal  
United States Senator

*Tammy Baldwin*

Tammy Baldwin  
United States Senator

*Chris Murphy*

Chris Murphy  
United States Senator

*Mazie Hirono*

Mazie K. Hirono  
United States Senator

*Edward J. Markey*

Edward J. Markey  
United States Senator