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October 21, 2016

The Honorable Loretta Lynch
Attorney General of the United States
Department of Justice
950 Pennsylvania Avenue
Washington, DC 20530

Dear Attorney General Lynch:

I am writing regarding the recently announced DOJ settlement with Mylan Pharmaceuticals for charges related to its incorrect classification of EpiPen in order to avoid paying millions of dollars in rebates owed to the Medicaid program. DOJ has released no information on this settlement. But an October 7, 2016, announcement by Mylan appears to announce the key details of this settlement.[1] If these details are correct, they reveal the settlement to be shamefully weak, with no criminal penalties and no deterrent value to prevent drug companies from engaging in abusive schemes to defraud Medicaid and rip off taxpayers.

The remainder of this letter provides details on my concerns.[2]

**The Medicaid Drug Rebate Program**

The Medicaid drug rebate program is designed to protect taxpayers from the high costs of prescription drugs. It requires that manufacturers of brand name drugs pay a minimum 23.1% rebate, and contains additional protections so that manufacturers refund taxpayers the difference if a brand-name drug's price rises at a pace that exceeds the inflation rate.[3] Generic drug manufacturers pay a significantly lower rebate, equal to 13% of the drug cost, and presently pay no inflation rebate.[4]

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[1] 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).

[2] Senator Blumenthal sent you a letter expressing his concern about this weak settlement last week. I share his concerns. Letter from Sen. Blumenthal to Attorney General Lynch (October 14, 2016) (http://www.blumenthal.senate.gov/imo/media/doc/10.17.16%20-%20DOJ%20Letter%20on%20Proposed%20Mylan%20Settlement.pdf).

[3] 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 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" (online at https://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

[4] Social Security Act § 1927(c)(3) (online at https://www.ssa.gov/OP_Home/ssact/title19/1927.htm). Beginning in January 2017, an inflation rebate will be added to the rebate for generic drugs. *See* Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 97: New*

**Misclassification of EpiPen as a Generic Drug and Its Impacts**

For a drug like EpiPen, which has increased in price by 300% between 2011 and 2015, the brand-name rebate would be composed of the 23% minimum rebate, plus the inflation-based rebate, and would be significantly higher than the 13% generic rebate. But on October 5, 2016, CMS revealed that "EpiPen has been reported [by Mylan] as a generic drug...[although] EpiPen ...meets the definition of a ...brand drug."[5] CMS also reported that the agency has, "on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs and has expressly told Mylan that the product is incorrectly classified."[6]

My staff has identified ten instances since 1995 in which the agency issued clear, public guidance on the proper Medicaid classification of brand and generic drugs, including five final rules and four manufacturer releases.[7] These CMS publications make clear that drug manufacturers are responsible for "ensur[ing] their drugs are correctly categorized."[8] Federal law also makes clear that drug manufacturers are subject to strict penalties should they provide

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*Additional Inflation-Adjusted Rebate Requirement for Non-Innovator Multi-Source Drugs* (April 15, 2016) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-097.pdf). Beginning in January 2017, under a provision enacted under the Bipartisan Budget Act of 2015, generic drug manufacturers will also have to pay an inflation-based rebate. P.L. 114-74 § 602.

[5] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at http://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20from%20CMS%2010.5.16.pdf), p. 2.

[6] *Id.*

[7] See Proposed Rule MB-046-P (September 19, 1995) (online at https://www.gpo.gov/fdsys/pkg/FR-1995-09-19/pdf/95-22860.pdf); Final Rule CMS-2238-FC (July 17, 2007) (online at https://www.gpo.gov/fdsys/pkg/FR-2007-07-17/pdf/07-3356.pdf); Interim Rule CMS 2238-IFC (March 14, 2014) (online at https://www.gpo.gov/fdsys/pkg/FR-2008-03-14/pdf/08-1022.pdf); Final Rule CMS-2238-F (October 7, 2008) (online at https://www.gpo.gov/fdsys/pkg/FR-2008-10-07/pdf/E8-23653.pdf); Final Rule CMS-2238-F2 (November 15, 2010) (online at https://www.gpo.gov/fdsys/pkg/FR-2010-11-15/pdf/2010-28649.pdf); Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 80* (January 5, 2010) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-080.pdf); Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 82: Incorrect Drug Product Information Reported to CMS* (November 1, 2010) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-082.pdf); Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 91* (September 12 ,2014) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-091.pdf); Final Rule CMS-2345-FC (February 1, 2016) (online at https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf); and Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 98: Drug Category Narrow Exception Guide* (May 2, 2016) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-098.pdf).

[8] *See* Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 91* (September 12 ,2014) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-091.pdf), p. 2-3; Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 82: Incorrect Drug Product Information Reported to CMS* (November 1, 2010) (online at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-082.pdf).

the Drug Rebate Program with false information.[9] Mylan had multiple opportunities, over multiple years, to ensure that the EpiPen was correctly categorized in response to direct guidance from CMS. There is no excuse for the company's misclassification of the EpiPen.

This misclassification has cost taxpayers hundreds of millions of dollars. The price of EpiPen increased from $137 per dose in January 2011 to $447 in December 2015 - a 326% increase.[10] Inflation during this same time period was minimal - the CPI increase over this time period was 7.7% total. If EpiPen had been correctly classified as a brand name drug, the Mylan would have paid an estimated rebate of approximately $416 per dose - reducing the cost by over 90%. But by classifying the drug as a generic, the rebate was only approximately $58 per dose.

CMS reported that Medicaid spent $961 million on EpiPen between 2011 and 2016, and that Mylan paid $164 million in rebates, lowering costs to $797 million.[11] CMS reported that "[t]his incorrect classification has financial consequences for the amount that federal and state governments spend," but declined to provide specific information.[12] My staff conducted additional calculations based on publicly available information. Based on these estimates, it appears that, as a result of the miscalculation, Mylan underpaid Medicaid rebates by an estimated $530 million - primarily due to the failure to pay the required inflation rebate.

**The EpiPen Medicaid Settlement Fails to Hold Mylan Accountable**

On October 7, 2016, Mylan announced the terms of a settlement with DOJ and other agencies regarding its classification of EpiPen and the resulting underpayment of rebates. DOJ has had no public announcement or comment. According to Mylan, the company will pay $465 million to settle the case. In addition, "[t]he terms of the settlement do not provide for any finding of wrongdoing on the part of Mylan Inc. or any of its affiliated entities or personnel. ...The settlement terms provide for resolution of all potential rebate liability claims by federal and state governments as to whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula."[13] And the payment will be a pre-tax payment - meaning the payment can be deducted from any corporate taxes owed by Mylan.[14]

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[9] Social Security Act § 1927(b)(c)(ii) (online at https://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

[10] Katherine Young and Rachel Garfield, "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/).

[11] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at http://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20from%20CMS%2010.5.16.pdf).

[12] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, to Senator Ron Wyden, Ranking Member, Senate Finance Committee (October 5, 2016) (online at http://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20from%20CMS%2010.5.16.pdf).

[13] 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).

[14] 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).

To summarize: if the terms of the agreement announced by Mylan are correct, Mylan wrongly classified EpiPen to maximize its Medicaid revenue, and did not change this classification despite being "expressly told" by CMS that it was wrong. The Justice Department has rewarded Mylan by imposing a fine that is about $65 million less than the amount Mylan made by defrauding Medicare and Medicaid. In addition, you permitted Mylan to avoid admitting any admission of wrongdoing, collected no additional penalties unde the False Claims Act, and blocked other actions against the company that would have required greater accountability.

This settlement is shockingly soft on this corporate wrongdoer. The Justice Department has extensive tools available to hold a company like Mylan accountable. The Medicaid drug rebate law contains large penalties for false classification or reporting - up to $100,000 per item of false information. The False Claims Act allows triple damages and has been extensively used in cases of Medicare and Medicaid fraud. The Health Care Fraud law contains criminal penalties - including prison terms of up to a decade - for knowingly and willfully defrauding a federal health care program.[15]

But it appears that none of these penalties was used against Mylan or its senior executives, despite the fact that the company was "expressly told" of its misclassification by CMS, despite the fact that this was the second time in less than a decade that the company was caught defrauding Medicaid[16] and despite the fact that the company made hundreds of millions of dollars on the backs of taxpayers. Your department's limp response to Mylan's deliberate fraud raises a serious question about exactly how you plan to police other companies if you approve settlements that show that crime does pay.

If the terms of the settlement announced by Mylan are accurate, the American public has a right to know why and how DOJ reached a settlement that failed to hold this corporate criminal accountable. I ask that you provide my staff with a briefing on this settlement no later than October 28, 2016.

Sincerely,

Elizabeth Warren
United States Senator

[15] 18 U.S.C. § 1347 (online at https://www.law.cornell.edu/uscode/text/18/1347).
[16] U.S. Department of Justice, "Four Pharmaceutical Companies Pay $124 Million for Submission of False Claims to Medicaid (press release)" (October 9, 2009) (online at https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-false-claims-medicaid).