United States Senate

WASHINGTON, DC 20510

September 28, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Loretta E. Lynch
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, Northwest
Washington, D.C. 20530

Dear Attorney General Lynch:

We write to inquire whether the Department of Justice has considered an investigation into whether Mylan Pharmaceuticals violated the law when it apparently misclassified its EpiPen product for purposes of the Medicaid Drug Rebate Program.

Congress created the Medicaid Drug Rebate Program to protect states from high pharmaceutical prices by requiring drug companies to pay a percentage of their revenues to states in the form of rebates. Crucially, the Medicaid Drug Rebate Program distinguishes between "innovator drugs"—new products that are generally insulated from generic competition by patents—and "non-innovator multiple source" (NIMS) drugs—older products that are available from multiple sellers. Companies pay a rebate of 13 percent of the price of non-innovator drugs. For innovator drugs, sellers pay a minimum rebate of 23.1 percent, but they can pay far more for drugs that experience large price hikes.

Pharmaceutical companies are responsible for determining whether their products are innovator or NIMS drugs. Companies can reap huge profits, at the expense of the states and taxpayers, by misclassifying innovator drugs as NIMS drugs. In the past, the Department has secured settlements against drug companies under the False Claims Act for such practices—including against Mylan Pharmaceuticals.[1]

Mylan has classified the EpiPen as a NIMS drug since acquiring the product license in 2007. According to press reports, however, the Center for Medicare and Medicaid Services (CMS) has stated publicly that this is incorrect.[2]

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[1] Press Release, United States Department of Justice, *Four Pharmaceutical Companies Pay $124 Million for Submission of False Claims to* Medicaid, https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-false-claims-medicaid.

[2] Insidehealthpolicy.com, *CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates*, https://insidehealthpolicy.com/daily-news/cms-tells-mylan-it-incorrectly-classified-epipen-pay-lower-medicaid-rebates-lawmakers; News Release, United States Senator Amy Klobuchar, *Klobuchar on the Drug Category Misclassification of Mylan*

The first indicator that the EpiPen should not be classified as a NIMS drug is the plain text of the relevant statute. Under section 1927(k)(7)(A) of the Social Security Act, for a drug to be classified as a NIMS there must be "at least 1 other drug product which . . . is rated as therapeutically equivalent.[3]" In other words, the NIMS drug must face an FDA-approved competitor. The EpiPen faces no such competitor, and it has not since Mylan began selling the product.

The second indicator comes from Mylan's own behavior. The Medicaid Drug Rebate Program imposes a higher rebate on innovator drugs because innovator drugs are generally protected by patents. Shortly after Mylan began marketing the EpiPen, it sued Teva Pharmaceuticals for patent infringement, leading to a settlement that kept Teva out of the EpiPen market until late 2015.[4] During this timeframe, Mylan increased its prices dramatically, including a rise from $265 to $609 in the last three years.[5]

Then, in 2015, Mylan filed a citizen's petition with the Food and Drug Administration (FDA) asking the agency not to grant "therapeutic equivalence" status to Teva's competitor product.

In support of its contention that the EpiPen is properly classified, Mylan relies on a 1997 HHS opinion provided to Dey Laboratories, then the marketer of EpiPens, stating that the EpiPen could be marketed as a NIMS drug. However, the EpiPen marketed by Mylan is significantly different than the 1997 version. Since 2008, the Mylan product has been protected by at least one additional patent.[6] The 1997 HHS opinion to Dey Laboratories may no longer be applicable given all of Mylan's alterations and additions since then. Further, it is our understanding that classifying the EpiPen as a non-innovator product is inconsistent with industry practice. When

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Pharmaceutical's EpiPen, http://www.klobuchar.senate.gov/public/news-releases?ID=A2D437E5-0B86-4250-AC6C-993EEBF92675.

[3] 42 U.S.C.A. § 1396r-8 (K)(7)(A).

[4] King Pharmaceuticals Inc. v. Teva Parenteral Medicines Inc., No. 09CV00652 (D. Del. Aug. 28, 2009) (available at https://1.next.westlaw.com/Document/Iecafa66e9c7311deb08de1b7506ad85b/View/FullText.html?navigationPath=Search%2Fv3%2Fsearch%2Fresults%2Fnavigation%2Fi0ad70525000001572a044da1ed656674%3FNav%3DPMM%26fragmentIdentifier%3DIecafa66e9c7311deb08de1b7506ad85b%26startIndex%3D1%26contextData%3D%2528sc.Search%2529%26transitionType%3DSearchItem&listSource=Search&listPageSource=7d998d4cee29de7c7cb454a0d317f505&list=PMM&rank=2&grading=na&sessionScopeId=93673de6b0412896ed556721f98e0f5faeab96a4503fc90fb73fda88bfaedc28&originationContext=Search%20Result&transitionType=SearchItem&contextData=%28sc.Search%29); First Amended Complaint, King Pharmaceuticals Inc. v. Teva Parenteral Medicines Inc., No. 09CV00652 (D. Del. Nov. 11, 2010) (available at https://1.next.westlaw.com/Document/I76830a00e9d511e0a9e5bdc02ef2b18e/View/FullText.html?navigationPath=Search%2Fv3%2Fsearch%2Fresults%2Fnavigation%2Fi0ad70525000001572a044da1ed656674%3FNav%3DPMM%26fragmentIdentifier%3DI76830a00e9d511e0a9e5bdc02ef2b18e%26startIndex%3D1%26contextData%3D%2528sc.Search%2529%26transitionType%3DSearchItem&listSource=Search&listPageSource=7d998d4cee29de7c7cb454a0d317f505&list=PMM&rank=6&grading=na&sessionScopeId=93673de6b0412896ed556721f98e0f5faeab96a4503fc90fb73fda88bfaedc28&originationContext=Search%20Result&transitionType=SearchItem&contextData=%28sc.Search%29.

[5] Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, N.Y. TIMES, Aug. 24, 2016, http://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?action=click&contentCollection=Business%20Day&module=RelatedCoverage&region=EndOfArticle&pgtype=article&_r=0.

[6] U.S. Patent Nos. 7449012, 7794432; U.S. Dept. of Health & Human Services, Food & Drug Administration, Approved Drug Products with Therapeutic Equivalent Evaluations (Orange Book) (available at http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Appl_type=N&Appl_No=019430&Product_No=002).

Mylan's competitors market a drug delivery product under a new drug application, at least some of them classify the product as an innovator, even if the drug being delivered is off-patent. As part of any investigation into Mylan, we encourage you to determine whether Mylan's conduct in this case is consistent with accepted market practice or an industry outlier.

The facts laid out above suggest that Mylan may have knowingly misclassified EpiPens, potentially in violation of the False Claims Act and other statutes. For example, a person may be subject to liability under the False Claims Act who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay" or who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay . . . money . . . to the Government."[7] A knowing misclassification of a drug subject to the rebate program could result in an incorrect, lower payment obligation to the Government program.[8] We suggest that the Department consider whether these or other provisions of the False Claims Act would apply to the facts in this case. The American people have been rightly outraged as Mylan engaged in substantial price increases that resulted in billions of dollars paid by U.S. consumers. They deserve to know whether the company also violated the False Claims Act and diverted millions of dollars from U.S. taxpayers.

We look forward to working with you on this important issue. Please respond no later than October 12, 2016. Please contact Sam Simon (Sam_Simon@judiciary-dem.senate.gov) or Khaliyl Lane (Khaliyl_Lane@blumenthal.senate.gov) in Senator Blumenthal's office, or Josh Flynn-Brown (Josh_Flynn-Brown@judiciary-rep.senate.gov) or DeLisa Lay (delisa_lay@judiciary-rep.senate.gov) in Senator Grassley's office, or Michael Kades (Michael_Kades@judiciary-dem.senate.gov) in Senator Klobuchar's office with any questions.

Sincerely,

RICHARD BLUMENTHAL
United States Senator

CHUCK GRASSLEY
United States Senator

AMY KLOBUCHAR
United States Senator

[7] 31 U.S.C. § 3729(a)(1)G).
[8] Press Release, United States Department of Justice, *Four Pharmaceutical Companies Pay $124 Million for Submission of False Claims to* Medicaid, https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-false-claims-medicaid.