

# United States Senate

WASHINGTON, DC 20510

March 9, 2017

The Honorable Maureen K. Ohlhausen  
Acting Chairman  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Dear Acting-Chairman Ohlhausen:

We write to commend the decision by the Federal Trade Commission (FTC) to launch an investigation of Mylan's business practices. The astronomically high cost of prescription drugs continues to burden families across the country, and Mylan has faced well-deserved scrutiny for the radical price increases it imposed on EpiPen users and its efforts to shield EpiPens from competition.

Epinephrine auto-injectors provide lifesaving care for those with severe allergies. In 2015 alone, nearly 3.6 million Epi-Pen prescriptions were written.<sup>1</sup> Mylan has, until recently, been able to supply this market with little to no competition. The company will now face competition from Kaleo's Auvi-Q injectors, which returned to market on February 14.<sup>2</sup> The Auvi-Q, which was recalled in 2015 following manufacturing problems, may cost as much as \$4,500 for a two-pack. CVS, in partnership with Impax Laboratories, is also offering an authorized generic of the AdrenaClick auto-injector. Mylan continues to be the only producer of a generic substitute for the EpiPen.<sup>3</sup>

Beginning last summer, we raised concerns about Mylan's conduct. In a series of letters to the company, we expressed concern regarding its significant price increases on the EpiPen, the reach of its patient assistance program, the lack of transparency in pricing decisions, the misclassification of the EpiPen under the Medicaid Drug Rebate program, and efforts to delay generic competition for EpiPens.<sup>4</sup>

In her letter, Senator Murray expressed concern about a 2012 settlement agreement that resulted in a several year delay in Teva bringing its generic auto-injector to market. Similar agreements have faced scrutiny because they allow branded drugs to continue their monopolies by delaying entry of generic competition into the marketplace. The Supreme Court has held that such agreements can create a "significant risk of unjustified anticompetitive effects in violation of federal antitrust laws."

In that letter, Senator Murray also expressed concern about Mylan's filing of a "Citizen Petition" opposing approval of Teva's epinephrine auto-injector. In 2015, before Teva gained approval for its generic auto-injector, Mylan urged the FDA to reject Teva's pending application. Mylan filed

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<sup>1</sup> <https://www.wsj.com/articles/mylan-faces-scrutiny-over-epipen-price-increases-1472074823>

<sup>2</sup> <http://www.marketwatch.com/story/rival-to-epipen-to-return-to-market-2017-01-19>

<sup>3</sup> <https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices>

<sup>4</sup> Letter from Senator Patty Murray, Ranking Member, Senate Committee on Health, Education, Labor, and Pensions, to Mrs. Heather Bresch, CEO, Mylan, Inc. (Sept. 27, 2016).

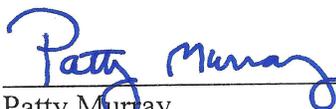
a Citizen Petition with the FDA, arguing that a design difference between Mylan and Teva's products meant they were not truly equivalent. Specifically, Mylan argued that EpiPen-trained users would not be able to safely and effectively use Teva's product with the EpiPen instructions. FDA ultimately identified "major deficiencies" in Teva's application, effectively delaying possible approval of Teva's product for at least a year.<sup>5</sup>

Similarly, in August, Senator Klobuchar wrote to the Commission asking for a broad-based investigation into whether Mylan had used anticompetitive activities to impose or protect its price increases.<sup>6</sup>

According to press reports, the FTC's recently launched investigation will examine Mylan's possible anti-competitive practices, including its efforts to block approval of Teva's generic version of the EpiPen.<sup>7</sup> Mylan may have made changes to its products to avoid competition from similar, low-priced products. The investigation may also examine whether the company engaged in agreements to delay cheaper version of its products from coming to market.

We again commend the FTC for its investigation of Mylan, and we urge the agency to closely scrutinize Mylan's anti-competitive business practices. More broadly, we appreciate the Commission's vigilance in policing anti-competitive practices in the pharmaceutical industry.<sup>8</sup> Misconduct of this kind has no place in a market so vital to the public health. The Commission has a long, nonpartisan tradition of aggressively investigating and enforcing the antitrust laws in the pharmaceutical industry. We hope that these recent actions underscore that this tradition will continue.

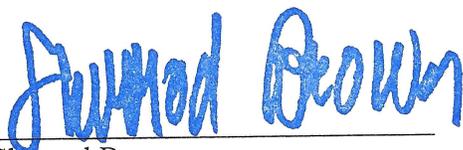
Sincerely,



Patty Murray  
United States Senator



Al Franken  
United States Senator



Sherrod Brown  
United States Senator



Tammy Baldwin  
United States Senator

<sup>5</sup> <https://www.bloomberg.com/news/articles/2016-03-01/mylan-s-epipen-gets-boost-as-fda-spots-holes-in-teva-application?cmpid=yhoo.headline>

<sup>6</sup> <https://www.klobuchar.senate.gov/public/2016/8/klobuchar-calls-for-ftc-investigation-of-mylan-pharmaceuticals-for-possible-antitrust-violations-in-light-of-dramatic-price-increase-of-epipen-packs>

<sup>7</sup> <https://www.wsj.com/articles/federal-trade-commission-questions-mylan-on-epipen-1485816270>

<sup>8</sup> For example, the Commission's investigation of Viropharma Inc. <https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes>



Amy Klobuchar  
United States Senator



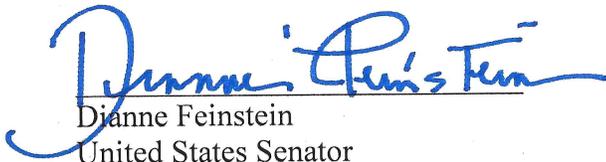
Richard Blumenthal  
United States Senator



Tammy Duckworth  
United States Senator



Kirsten Gillibrand  
United States Senator



Dianne Feinstein  
United States Senator