

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

August 8, 2017

Heather Bresch
Chief Executive Officer
Mylan
1000 Mylan Blvd
Canonsburg, PA 15317

Dear Ms. Bresch:

On March 28, 2017, I wrote to request information from Mylan related to the sales, marketing, and educational strategies the company has employed to promote opioid use.¹ Specifically, I requested information concerning internal estimates of addiction, compliance audits, marketing plans, continuing medical education materials and other presentations to physicians, expenses and quotas for speakers programs, and donations to third-party advocacy groups, among other issues. In my letter, I noted the staggering cost the ongoing opioid epidemic has imposed on the United States—including more than 15,000 fatal overdoses involving prescription opioids in 2015 alone.²

In an unsigned response, Mylan declined to produce documents or information in response to my requests. Although Mylan has conceded that “[o]pioid abuse is a very serious public health issue which warrants study of the entire opioid supply chain, including but not limited to manufacturers,” the company is the only recipient of my March 28 requests to refuse to cooperate with this inquiry.

Mylan has made this decision against the backdrop of ongoing U.S. investigations and lawsuits concerning its practices. In December 2016, for example, 20 states filed a civil complaint alleging that Mylan and two other companies “knowingly agreed to allocate and divide the market for the generic drug Doxy DR.”³ In January 2017, Mylan also received a request for information from the Federal Trade Commission, which is investigating potential antitrust violations in connection with the company’s EpiPen product.⁴ In a related action in

¹ Letter from Sen. Claire McCaskill to CEO Heather Bresch (March 28, 2017).

² Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (www.cdc.gov/drugoverdose/data/overdose.html).

³ Amended Complaint (March 1, 2017), *State of Connecticut, et al. v. Aurobindo Pharma USA, Inc., et al.*, D. Conn. (No. 3:16-cv-002056) (updated with 20 additional states); *see also 20 States Accuse Generic Drug Companies of Price Fixing*, New York Times (Dec. 15, 2016).

⁴ *Mylan Faces U.S. Antitrust Investigation on EpiPen*, Bloomberg (Jan. 30, 2017) (www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices).

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April, the French drugmaker Sanofi filed suit against Mylan, alleging that the company “engaged in illegal conduct to squelch...nascent competition” against EpiPen, “harming both Sanofi and U.S. consumers.”⁵ The same month, a class-action lawsuit alleged Mylan had illegally inflated the price of EpiPens through its partnerships with pharmacy benefit managers.⁶ And in May 2017, Sen. Grassley reported that Mylan may have overcharged U.S. taxpayers “by as much as \$1.27 billion over the course of a decade” for EpiPens—almost three times the settlement amount Mylan announced it would pay the federal government in October 2016.⁷

These actions have raised serious concerns about Mylan’s commitment to corporate compliance. Major pension funds and long-term shareholders, for example, recently alleged that Mylan “has a costly reputation for poor corporate governance.”⁸ The fact that the company has flatly refused to respond to my requests—despite acknowledging the severity of the opioid epidemic and the need to study the role of manufacturers—does nothing to dispel these concerns. Mylan’s decision to obstruct basic oversight related to an ongoing crisis should deeply concern the American people, the federal government, and shareholders as they consider the company’s role in the pharmaceutical industry. I again urge you to cooperate fully with this important inquiry.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman

⁵ *Mylan Tried to ‘Squelch’ EpiPen Rival, Sanofi Says in Lawsuit*, Bloomberg (Apr. 24, 2017) (www.bloomberg.com/news/articles/2017-04-24/mylan-tried-to-squelch-epipen-rival-sanofi-says-in-lawsuit).

⁶ *Mylan Hit with Racketeering Suit Over Big Price Hikes of EpiPen*, CNBC (Apr. 3, 2017) (www.cnbc.com/2017/04/03/mylan-hit-with-racketeering-suit-over-big-price-hikes-of-epipen.html).

⁷ *Taxpayers May Have Overpaid by More Than \$1 Billion for Mylan’s EpiPen, Senator Reveals*, CNBC (May 31, 2017) (www.cnbc.com/2017/05/31/taxpayers-may-have-overpaid-by-more-than-1-billion-for-mylans-epipen-senator-reveals.html).

⁸ Letter from Scott M. Stringer, New York City Comptroller, et al., to Mylan N.V. Shareowners (May 30, 2017).