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United States Senate

CHRISTOPHER R. HIXON, STAFF DIRECTOR MARGARET E. DAUM, MINORITY STAFF DIRECTOR

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS WASHINGTON, DC 20510–6250

September 28, 2017

Kåre Schultz CEO Teva Pharmaceutical Products Ltd. 1090 Horsham Road North Wales, PA 19454

Dear Mr. Schultz:

On July 26, 2017, I wrote to request information from Teva related to efforts the company has undertaken to detect, investigate, and report suspicious orders of opioid products. Specifically, I requested information concerning Teva programs to analyze "chargeback" requests, correspondence with distributor partners, reports of suspicious opioid orders originating from Missouri, and outcomes of investigations into Missouri-based pharmacies, distributors, and other customers. 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.

In a response on August 30, 2017, Teva provided general information regarding its antidiversion systems and procedures, including its efforts to address suspicious orders of opioid products. The company did not, however, provide responses to my specific requests or to requests for information my staff issued following a briefing from the company on July 24, 2017. Although Teva has stated it "remains fully committed to being a collaborative partner in addressing any opioid misuse," the company is the only recipient of my July 26 requests to indicate it will refuse to cooperate fully with this inquiry.

Teva has made this decision at a time when its senior officials have pledged to "continue to take action to aggressively confront our challenges." These challenges include multiple lawsuits, including a complaint from the State of Ohio, concerning the sales and marketing

<sup>&</sup>lt;sup>1</sup> Letter from Sen. Claire McCaskill to Interim CEO Dr. Yitzhak Peterburg (July 26, 2017).

<sup>&</sup>lt;sup>2</sup> Letter from James W. Matthews, Foley & Lardner LLP, to Sen. Claire McCaskill (Aug. 30, 2017).

<sup>&</sup>lt;sup>3</sup> Pharma Giant Teva's Troubles Were Predicted. The Path to Recovery Could Be Rocky, Fortune (Aug. 7, 2017) (fortune.com/2017/08/07/teva-stock/).

Kåre Schultz September 28, 2017 Page 2

techniques Teva has employed to promote its opioid products.<sup>4</sup> The July 2017 settlement between the Department of Justice and Mallinckrodt Pharmaceuticals—in which the company paid \$35 million to resolve allegations that it "did not meet its obligations to detect and notify DEA of suspicious orders"—has also focused attention on other high-volume generic opioid manufacturers like Teva.<sup>5</sup> At the very least, as I noted in my July 26 letter, this settlement raises serious concerns about whether opioid manufacturers have complied with their anti-diversion obligations under the law.

The fact that Teva has flatly refused to response to my specific requests does nothing to dispel these concerns. More broadly, the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders as the company attempts to address larger management issues. I urge you to cooperate fully with this important investigation, and I invite you to contact my office by October 5, 2017, to make arrangements for doing so.

Sincerely,

Claire McCaskill Ranking Member Carlia

cc: Ron Johnson Chairman

<sup>&</sup>lt;sup>4</sup>Ohio Attorney General Sues 5 Pharma Companies Over Their Role in the Opioid Epidemic, CNBC (May 31, 2017) (www.cnbc.com/2017/05/31/ohio-ag-sues-pharma-companies-over-their-role-in-the-opioid-epidemic.html).

<sup>&</sup>lt;sup>5</sup> Department of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017) (www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).