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DEMOCRATIC WHIP

COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

United States Senate
Washington, DC 20510–1304

June 4, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

I write today to request information regarding the ongoing challenges that families nationwide are facing with respect to obtaining EpiPens and to urge the Food and Drug Administration (FDA) to take any and all steps necessary to quickly remedy this situation.

Last month, FDA added EpiPen 0.3 mg and EpiPen Jr. 0.15 mg, as well as generic versions of these products, to its list of drug shortages, due to supply disruptions and manufacturing delays at Pfizer's Meridian Medical Technologies. A recent survey by the Food Allergy Research and Education (FARE) organization found that more than 400 patients in 45 states are having difficulty obtaining EpiPens at their pharmacies, including some families in Illinois. EpiPens are vital for the 15 million Americans who suffer from food allergies, including one in 13 children. Therefore, any shortage or inability to obtain this product puts lives needlessly at risk.

Our federal agencies must do everything within their power to quickly and efficiently assist the manufacturers in rectifying their EpiPen shortage situation. Failure to do so could result in loss of life. In order to better understand this situation and how FDA is responding, I would appreciate answers to the following questions.

1) When and how did FDA first become aware of delays related to Pfizer's manufacturing of EpiPens?

2) What specific "manufacturing delays" are related to this shortage?

3) How long does FDA expect this EpiPen shortage will last and what steps is FDA taking to ensure patients continue to have access to epinephrine auto-injectors?

4) It is my understanding that, last fall, FDA warned Pfizer that Meridian Medical Technologies (which manufactures EpiPens) was in violation of good manufacturing practices and had failed to investigate serious product failures associated with patient deaths and severe illness. Please provide specifics about this warning. Have any patients died or been seriously sickened due to EpiPen failures?

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5) Is there anything that Congress could or should do to assist FDA in responding to this shortage and/or prevent future shortages of life-saving medications?

Thank you for your immediate attention to this important issue and please do not hesitate to contact me with any questions, or if I can assist in any way.

Sincerely,

Richard J. Durbin
United States Senator