RICHARD J. DURBIN
ILLINOIS
DEMOCRATIC WHIP

United States Senate
Washington, DC 20510–1304

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

June 4, 2018

James H. Miller
President and Chief Executive Officer
Meridian Medical Technologies, Inc.
6350 Stevens Forest Road, Suite #301
Columbia, MD 21046

Dear Mr. Miller:

I write today to request information regarding the ongoing challenges that families nationwide are facing with respect to obtaining EpiPens, which are manufactured by Pfizer's Meridian Medical Technologies, Inc.

Last month, the Food and Drug Administration (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. 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.

It is my hope and expectation that Meridian Medical Technologies is doing everything within its power to quickly and efficiently rectify this EpiPen shortage situation and prevent any future shortages of this life-saving product. Failure to do so could result in loss of life. In order to better understand this situation and how your company is responding, I would appreciate answers to the following questions by June 25, 2018.

1) When did Meridian Medical Technologies first become aware of manufacturing delays related to EpiPens?

2) When did you inform FDA of manufacturing problems related to EpiPens?

3) What specific manufacturing delays are related to this shortage?

4) How long does your company expect this EpiPen shortage will last and what steps are you taking to ensure patients continue to have access to epinephrine auto-injectors throughout the duration of this shortage?

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5) 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 and any steps that you took to address FDA's concerns.

6) Have any patients died or been seriously sickened due to EpiPen failures?

7) What steps is your company taking to ensure this never happens again?

Thank you for your immediate attention to this important issue and please do not hesitate to contact my office with any questions.

Sincerely,

Richard J. Durbin
United States Senator