

United States Senate

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The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

Dear Secretary Azar,

I write to you regarding the persistent, serious shortage of the widely used EpiPen Auto-Injector as we begin a new school year. As you know, this lifesaving drug provides treatment and security to millions of Americans, including children, who suffer from severe allergies. The prolonged shortage of EpiPen is simply unacceptable. I urge the Department of Health and Human Services (HHS) to work with insurers to help make available epinephrine auto-injectors, whether domestic or imported, so that children and families can access these lifesaving products as this unacceptable shortage persists.

When I wrote to FDA Commissioner Gottlieb in May, I expressed my frustration that this current shortage has persisted. Despite assurances that the shortage was occurring on an "intermittent" or "isolated" basis, evidence has showed the shortage is much more widespread. Further, FDA declared in early May that it anticipated this shortage to be "short-term" based on assurances from manufacturers.¹ Unfortunately, as August ends, press reports and patient accounts prove that this is not the case.²

In the coming weeks, more than 6 million families will be restocking on their epinephrine supplies as children go back to school.

While I am encouraged by the fact FDA recently approved the first generic epinephrine auto-injector, this product may not become available to consumers in the near future.³ Further, while FDA recently extended the expiration date on some EpiPens to help mitigate the shortage⁴, more can and must be done.

¹ Rony Caryn Rabin, "Consumers Struggle to Find EpiPens," *The New York Times*. May 10, 2018.

² Rachel Siegel and Carolyn Y. Johnson, "EpiPen shortage raises alarm for parents as kids head back to school," *The Washington Post*. Aug. 16, 2018.

³ Carolyn Y. Johnson and Laurie McGinley, "FDA approves first generic version of EpiPen," *The Washington Post*. Aug. 16, 2018.

⁴ Maggie Fox, "FDA extends EpiPen expiration dates to cover shortages," *NBC News*. Aug. 21, 2018.

First, as FDA did with intravenous (IV) saline following Hurricane Maria, the safe importation of approved epinephrine auto-injectors from foreign countries should be approved to immediately combat the effects and duration of the shortage. The imports provided temporary relief to hospitals and other facilities. Individuals and families deserve this same relief and reassurance now with epinephrine auto-injectors.

Second, as this shortage of EpiPens persists, consumers should have access to all epinephrine auto-injectors that are currently available and not in shortage. Unfortunately, many families are finding that when alternatives to the EpiPen are available, their insurance company does not cover the cost, forcing them to either pay entirely out of pocket or go without the product. The Centers for Medicaid and Medicare Services (CMS) must call on insurers to add any epinephrine auto-injector that is not in shortage to their formularies and make those products available to consumers at the lowest level of cost-sharing. CMS must also ensure that state Medicaid programs, Medicare, and Medicare Advantage plans also offer available alternatives to the EpiPen at the lowest cost possible to consumers.

I implore you, on behalf of patients in Connecticut and throughout the country, to take these actions to help alleviate the effects of this shortage, and constantly and doggedly work with the manufacturers of EpiPen to bring it to an end. As children head back to school, we can and must do better to ensure that every person who needs this lifesaving device can access it easily and affordably.

Sincerely,



Senator Richard Blumenthal
United States Senate