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Congress of the United States
House of Representatives
Washington, DC 20515

November 21, 2019

President Donald J. Trump
The White House
1600 Pennsylvania Avenue N.W.
Washington, D.C. 20500

Dear Mr. President:

Insulin was discovered nearly a century ago and there are no active patent protections on any current insulin product. Nevertheless, only three companies manufacture this life-saving drug on which 30 million Americans rely, and only one is based in the United States. To date, there are no generic insulin options available as there are for many other expensive drugs.

Because of this lack of competition, the price of insulin has risen 700% since 2001. As a result, at least one in four Americans with type 1 diabetes are dangerously rationing their supply, which often leads to cascading health problems or death. This harsh reality can only be described as a healthcare crisis.

An affordable generic insulin option is closer to market than ever before, but regulatory barriers at the U.S. Food and Drug Administration (FDA) and current federal law are standing in the way. In 2017, the FDA released a list of synthetic peptide drug products eligible for generic approval through the Abbreviated New Drug Application (ANDA) process, the approval path traditionally used for generic substitutes to brand-name drugs. Insulin (a complex peptide) and its analogues were omitted from this list.

Generic drugs are identical copies of brand-name drugs and often much more affordable. For too long, diabetics, their families and loved ones, and public policymakers have begged the question – "Why is there no generic insulin?" Drug manufacturers say they now have the capability using chemical synthesis technology to produce a true generic insulin.

Mr. President, you can take decisive, executive action to begin fixing this problem. You can help those suffering from diabetes in America who cannot afford life-saving insulin. Specifically, I urge you to:

1. Exercise your legal authority under Section 319 of the Public Health Service Act to direct the Secretary of the Department of Health and Human Services to declare the nationwide lack of affordable insulin to be a public health emergency and, based on this declaration, issue an Executive Order directing the FDA to add insulin and its analogues to the

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aforementioned list, which would give generic drug makers a clear regulatory path for filing for approval until March 23, 2020.

2. Encourage Congress to act to pass H.R. 4244, the *Market Access for Generic Insulin Competition (MAGIC) Act*, which I introduced in September. My bill would establish a permanent pathway for the approval of generic insulin.

The MAGIC Act is crucial. The *Biologics Price Competition and Innovation Act of 2009*, enacted as part of the *Patient Protection and Affordable Care Act*, mandates that on March 23, 2020, insulin will be removed from the FDA's list of approved drug products (also known as the Orange Book) and officially reclassified as a biological product (in the Purple Book). As a result, drug manufacturers will be statutorily barred by law from applying to make a generic insulin product of any kind. Instead, the only path for producing a generic insulin alternative will be to seek a new drug approval for "biosimilar" insulin. As the name suggests, biosimilars are close to the reference product but are not fully identical copies. Therefore, generic insulin manufacturers will be forced to pursue a new, expensive, years-long application process that includes animal and human drug trials designed for new drug approvals rather than approval of a scientifically identical generic product. There is little doubt that such a process will lead to a delay in much-needed competition in the insulin market. In the meantime, diabetics and their families and loved ones will continue to suffer.

Again, you have the authority to make a difference by issuing the Executive Order outlined above. Coupled with congressional passage of H.R. 4244, a clear and permanent pathway would be established for the approval of true generic insulin. Please note that my legislation would not hinder or otherwise affect the approval of biosimilar insulin in any way. The more competition in the insulin market, the better.

Thank you for considering this time-sensitive request. The March 23, 2020, transition date is a mere four months away, and diabetics need help now. I look forward to working with you and my colleagues in Congress on this matter of critical importance to millions of Americans.

Sincerely,

Mike Kelly
Member of Congress