Congress of the United States

Washington, DC 20515

September 20, 2017

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket # FDA-2017-N-3615 for "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments"

To Commissioner Gottlieb:

As Co-Chairs of the Congressional Diabetes Caucus, we are gravely concerned about the rising costs of insulin, which have made this lifesaving medication unaffordable for many people with diabetes. We write today to ask the Food and Drug Administration (FDA) to consider moving forward with policies that would reduce barriers to market entry for lower-cost, biosimilar versions of insulin as part of your efforts to balance innovation and access.

Over the last ten years, the average cost of insulin has tripled and is now an average of $287.22 per month for diabetes patients. There are multiple factors driving the ongoing rise in drug prices, in addition to pharmaceutical companies raising the price. Many patients are becoming more exposed to high drug prices due to high deductibles, coinsurance, and various formulary exclusions. Unfortunately, this growing, direct cost burden negatively impacts millions of diabetes patients. We have heard personal stories from people across the diabetes community who struggle to purchase insulin due to prohibitive costs. Insulin is a life-sustaining treatment and patients should not be forced to choose between medication and other basic necessities.

We applaud FDA, under your leadership, for convening the July 18 public meeting, "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access," and for examining ways to ensure the balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained.[1] We also appreciate your work on the "Drug Competition Action Plan"[2] and, as part of these efforts, we request your consideration of policy solutions that will make insulin more affordable for all Americans who need it.

Over the last several months, we have met with a broad range of stakeholders on how to address the vexing problem of rising insulin prices and the burden it imposes for millions of

[1] https://www.fda.gov/Drugs/NewsEvents/ucm563986.htm
[2] https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/

diabetes patients. One of the recommendations we would encourage the FDA to make as part of your ongoing work is to amend and finalize the March 2016 draft guidance on the implementation of the "deemed to be a license" provision of the Biologics Price Competition and Innovation Act of 2009.[3] It is our understanding that the lack of certainty on the guidance may be causing unnecessary delays to patient access to lower-cost versions of biological medicines and, in particular, insulin products.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) directed the transition of certain protein products traditionally approved under the Food, Drug and Cosmetic Act to biological products under the Public Health Service Act starting on March 23, 2020. In other words, any application approved prior to the March 23, 2020 date shall be "deemed to be a license" as a biologic and allowed to maintain its status as a marketable product available to patients. Insulins are the largest category of products impacted by the "deemed to be a license" provision. The draft guidance issued last year, however, unnecessarily delays market entry for competitive products that could help lower the cost of insulin.

We have heard concerns that the draft guidance would require re-submission of any pending applications not approved by March 23, 2020, including those for which FDA's scientific review is complete and that have been tentatively approved. Due to the costs associated with submitting an application and the timeline for FDA approval, there is a concern that this will cause manufacturers to wait until after March 23, 2020 to start the process, rather than seek approval today. We believe the draft guidance should be amended to streamline the transition to ensure patient access to more affordable biosimilar treatments, reflecting the Congressional intent of BPCIA. Without this clarity, we are concerned that access to more affordable insulin treatments may be unnecessarily delayed for years.

The FDA's effort to examine regulatory barriers is critical to ensuring the right balance is struck between innovation and access. As we have seen over the last decade, competition is necessary to ensuring patient access to affordable medications. Each year of delayed competition results in higher costs to patients and taxpayers. We believe this market dynamic applies to the price on insulin and further delays could result in diabetes patients paying more.

Thank you again for your leadership and attention to these issues. We appreciate any efforts the FDA can take to provide clarity, streamline the process, and ensure diabetes patients are provided with timely access to more affordable biosimilar and insulin treatments. Please do not hesitate to contact Logan Hoover in Rep. Reed's office (logan.hoover@mail.house.gov or 202-225-3161) or Polly Webster in Rep. DeGette's office (polly.webster@mail.house.gov or 202-225-4431) with any questions.

Sincerely,

TOM REED
Member of Congress

DIANA DEGETTE
Member of Congress

[3] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM490264.pdf