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SUBCOMMITTEE ON SOCIAL SECURITY, REPUBLICAN LEADER
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON WORKER FAMILY SUPPORT

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July 31, 2019

Norman Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Sharpless,

As Co-Chairs of the Congressional Diabetes Caucus, we are writing to follow up on our letter dated 9/20/2017 regarding our concern with the Food and Drug Administration's (FDA) guidance and implementation of the "deemed to be a license" provision of the Biologics Price Competition and Innovation Act of 2009. We continue to hear from stakeholders who are concerned about this guidance and ask the FDA to provide clarity and certainty to the market to allow for swift integration of biosimilars into the insulin market.

Each day, too many Americans are forced to make a choice between paying for insulin and paying for other necessities like food and housing. Worse, they are forced to ration their insulin causing horrible health ramifications, hospitalizations, and in some cases, death. We have to do better. We are hopeful that new insulin biosimilars will provide additional options and competition into the market to drive the cost of insulin down.

While the FDA has made considerable progress towards this goal, we are extremely concerned that FDA's interpretation of the *Biologics Price Competition and Innovation Act of 2009* has caused manufacturers to delay submitting applications for follow-on insulin products until after the March 23, 2020 transition date, when these new products will be deemed to be biologics. Many manufacturers are concerned that if their applications are not reviewed and approved by this deadline, they will be forced to start from scratch and reapply. Both the uncertainty and the potential risk of having to restart have caused and will continue to cause an unnecessary delay in bringing these innovative new drugs to market.

We ask that the Food and Drug Administration (FDA) take concrete, immediate steps to reduce or eliminate any hurdles associated with bringing lower-cost insulin to market. We encourage you to bring some clarity to this issue by working with manufacturers with pending applications to ensure that a final decision is made before the March 23rd deadline and create a pathway for those applications that don't meet the deadline to continue on without having to restart.

By taking these actions, we'll bring some certainty to the manufacturers and prevent the delay of much-needed competition to the market. Thank you again for your leadership on this issue. We look forward to working with you to bring more affordable insulin to all patients who need it. Should you have any questions please don't hesitate to contact Logan Hoover in Rep. Reed's office (Logan.Hoover@mail.house.gov or 202-225-3161) or Sherie Lou Santos in Rep. DeGette's office (SherieLou.Santos@mail.house.gov or 202-225-4431). We appreciate your consideration of this matter.

Sincerely,

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