U.S. Rep Grothman: Introduces bill to increase insulin competition and affordability

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(Washington, D.C.) – Congressmen Glenn Grothman (WI-06) introduced legislation to help increase competition in the insulin market, expand availability to affordable insulin products and lower costs to patients who depend on insulin.

The Biosimilar Insulin Access Act will waive interchangeability requirements for insulin products granted biosimilar approval by the Food and Drug Administration (FDA). This would enable pharmacists to dispense and patients to choose which biosimilar insulin product works best for their individual needs instead of being forced to pay top-dollar for brand-name insulin, or a reference product. This is an idea that has been covered by the Center for Biosimilars, New England Journal of Medicine and one the FDA has indicated interest in pursuing.

According to the Center for Biosimilars, the annual cost of insulin for a patient with Type 1 diabetes doubled from $2,864 in 2012 to $5,705 in 2016. While it has been estimated that FDA-approved biosimilars could save patients and the health care system anywhere from $54 to $250 billion over their first 10 years on the market, these cost savings have yet to be achieved due to a slow moving approval process, patent considerations and anti-competitive strategies.

The Biosimilar Insulin Access Act would be a milestone for the biologic industry, as it would allow an FDA approved biosimilar insulin to be the first biosimilar product with an interchangeable designation.

“There are over 34 million diabetes patients in the U.S. and for many of them, having insulin is as important as breathing,” **said Grothman**. *“The way the system is set up, however, the deck is stacked in favor of more expensive brand-name products.*

“The Biosimilar Insulin Access Act will enable the FDA to quickly and safely make biosimilar insulin products, that are cheaper but every bit as effective as brand-name insulin, more widely available to patients who want it. We owe it to Americans to fix our broken health care system. Having biosimilar insulin products more widely available will create competition in the market, which can drive down costs, increase quality and finally give patients with Diabetes greater choice and flexibility in their treatment.”

Background Information

There are two types of drugs: chemical and biologic. Chemical drugs, such as Tylenol, can be easily replicated because they are manufactured by combining chemical compounds in a structured process. Replications of chemical drugs are called “generics”.

Biologics, such as insulin, can be replicated as well, but involve complex mixtures of molecules and require a much lengthier manufacturing process. Biologic drugs that have the same effect as their reference drug are called “biosimilars”. Biosimilars can be thought of as a generic option for a biologic drug.

On March 23, 2020, the FDA transitioned biologics previously classified and approved as large molecule chemical drugs under the Federal Food, Drug and Cosmetic Act (FD&C Act) to the Public Health Service (PHS) Act through a Biologics License Application (BLA). Transitioning these biologic products previously classified under the FD&C Act to the biologic’s pathway opens insulin products for biosimilar approval and competition, something the insulin market in the United States has severely lacked for decades.

Biosimilars must have the same mechanism of action, route of administration,

dosage form and strength as the original reference biological product. Before approving a biosimilar, FDA experts must conclude it is “highly similar” to the original biologic and that it has “no clinically meaningful differences” from the original biologic. This means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would from the reference product. The same quality manufacturing standards that apply to the original biologic also apply to the biosimilar.

After receiving biosimilar approval, manufacturers can apply for an interchangeable designation. An interchangeable product may be automatically substituted for the reference product at the pharmacy counter; however, they require rigorous and lengthy trials including several switches between the reference product and biosimilar in clinical trials to determine whether any difference is noticed over the course of treatment. As of 2019, all but five states had biosimilar interchangeability laws, all of which require patient and physician consent prior to dispensing an interchangeable product.

While standard interchangeability requirements for biosimilars dealing with more complex and less understood conditions are necessary, the long history of diabetes treatment and insulin regulation suggests the interchangeability process for biosimilar insulin products should be abbreviated.

The Biosimilar Insulin Access Act would waive interchangeability requirements for insulin products granted biosimilar approval by the FDA. If an insulin product achieved approval from the FDA to be licensed and marketed as a biosimilar to its reference product, that insulin product would be deemed interchangeable as well. The FDA has approved 28 products as biosimilars up to this point, however, none of those products have been granted interchangeable designation. This bill will allow these insulin products to be automatically substituted at the pharmacy counter for their reference product at the patient and physician’s decision. Streamlining interchangeability for biosimilar insulin products is broadly supported by physicians and pharmacists across the United States. This legislation would dramatically increase competition in the insulin market and give physicians and pharmacists the ability to dispense lower cost options to patients.