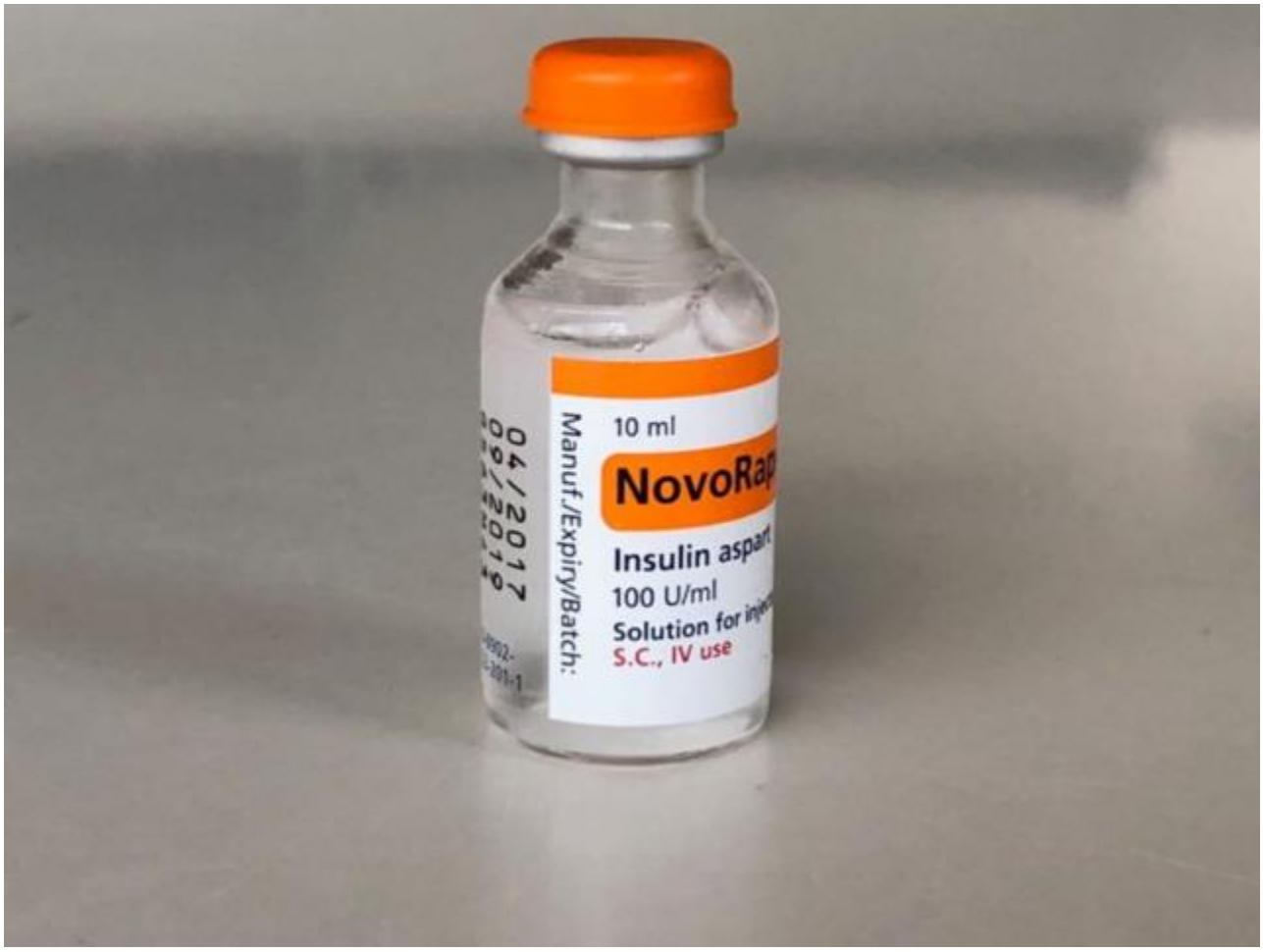
Durbin, Cramer, Smith Introduce Bill to Speed Up Availability of Generic Insulin

July 17 2019 10:41 AM



WASHINGTON – U.S. Senators Dick Durbin (D-IL), Kevin Cramer (R-ND), and Tina Smith (D-MN) today introduced the Affordable Insulin Approvals Now Act, a bipartisan bill to speed up approvals of lower-cost, generic, and “follow-on” insulin products in order to help lower costs of the life-saving drug.

Approximately 7.5 million Americans with diabetes rely on insulin every day to survive, yet the drug has experienced a price increase of more than 600 percent over the past two decades in the United States. Today's legislation would lower the price of insulin by promoting competition and bringing lower-cost generic products to market sooner—specifically by requiring FDA to continue reviewing generic insulin applications even after the agency's currently planned March 2020 cut-off date.

"America's insulin pricing scandal is a disgrace. Basic insulin was first discovered nearly a century ago, yet Big Pharma's price gouging is driving families and children to extraordinarily dangerous lengths – like rationing supplies – in order to afford a medication they need to survive. If we can create a faster path for FDA approval of generic insulin, we can finally help to lower costs and tell Big Pharma enough is enough," Durbin said.

"More generic insulin in the market means lower costs for those in need. Our bill encourages competition and free-market solutions to the rising cost of this life-saving drug," said Cramer.

"People with diabetes in Minnesota and across the country who need insulin to survive should not be forced into economic distress or dangerous rationing practices to afford Big Pharma's skyrocketing prices," said Smith. "By speeding up the FDA approval process to bring low-cost insulin products to market, we can make this life-sustaining medication more accessible and affordable for families."

In December 2018, FDA issued guidance to clarify the implementation of the Biologics Price Competition and Innovation Act. While the intent of this action is to ease the approval pathway for lower-cost biosimilar products, it creates a perverse incentive that could delay approval of "generic" insulin. FDA's new guidance effectively creates an application termination cliff on March 23, 2020—in which FDA will automatically reject "generic" insulin products that are in the approval pipeline during that time. As a result, this could delay approval of lower-cost insulin products for American patients.

Insulin was first discovered in 1921. The Nobel Prize-winning researchers sold the patent to the University of Toronto for just $1 because they believed that insulin should be made widely available to everyone, without worrying about the cost. However, the price of insulin today is the subject of anti-competitive practices and constant price increases.

There are only three primary insulin manufacturers in the U.S., Novo Nordisk, Eli Lilly, and Sanofi. Lantus, popular long-acting insulin, cost $35 when it was first introduced in 2001. Within the past few years, the price of a Lantus vial has skyrocketed to more than

$372, while that same exact drug was sold in France for $46, and $67 in Canada. The United States represents only 15 percent of the global insulin market, yet generates nearly half of pharma’s revenue on insulin.

Thirty million Americans are living with type I or II diabetes. Approximately 7.5 million of them rely on insulin to manage their blood sugar levels, and it is essential to their survival.

The legislation is supported by Diabetes Patient Advocacy Coalition, the National Diabetes Volunteer Leadership Council, and Children with Diabetes.