



# **Durbin, Cramer, Smith Applaud Inclusion Of Bill To Lower Cost Of Insulin For Patients In Year-end Funding Bill**

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WASHINGTON – U.S. Senators Dick Durbin (D-IL), Kevin Cramer (R-ND), and Tina Smith (D-MN) today applauded the inclusion in the Fiscal Year (FY) 2020 appropriations bill of their *Affordable Insulin Approvals Now Act*, a bipartisan bill to speed up approvals of lower-cost, generic insulin products in order to help reduce prices of this life-saving medication for patients. 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.

“Big Pharma’s insulin price gouging is driving families and children to extraordinarily dangerous lengths – like rationing dosages– in order to afford a lifesaving medication. I’m pleased my bipartisan bill to accelerate FDA’s review and help lower the cost of insulin will become the law of the land,” Durbin said.

“Increasing the amount of generic and low-cost insulin in the market will decrease the burden placed on patients who rely on these drugs,” said Cramer. “I am pleased to see our bipartisan bill included in this package, and I plan to keep working to find more ways to encourage competition and free-market solutions to the rising cost of health care.”

“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 successfully securing our measure in this spending package to speed up the FDA approval process and bring low-cost insulin products to market, we’re taking steps to make this life-sustaining medication more accessible and affordable for families nationwide.”

This bill will 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.

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 in the long-run, it created 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 the approval of lower-cost insulin products for American patients for months or years.

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.

Joining Durbin, Cramer, and Smith in cosponsoring the legislation include Senators Cindy Hyde-Smith (R-MS), Jeanne Shaheen (D-NH), Shelley Moore Capito (R-WV), Doug Jones (D-AL), Mitt Romney (R-UT), Sherrod Brown (D-OH), Lisa Murkowski (R-AK), Jeff Merkley (D-OR), Mike Braun (R-IN), Gary Peters (D-MI), Roger Wicker (R-MS), Kyrsten Sinema (D-AZ), John Hoeven (R-ND), and Cory Gardner (R-CO).

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