

***Patient Access to Drugs in Shortage Act***  
*Join me as an Original Cosponsor*

Dear Colleague:

Please join me in ensuring medical patients across the country continue to have access to lifesaving cancer treatments and are not adversely impacted by drug shortages. While both the Administration and Congress have taken steps to address the symptoms of drug shortages once they occur, action must be taken to address the true economic roots of the crisis to prevent future shortages. In the coming days I will be introducing the *Patient Access to Drugs in Shortage Act* which will tackle the root cause of the drug shortage problem – instability within the payment system.

Drug shortages in the generic injectable market have become more pronounced over the last few years. There were 211 new drug shortages in 2011 as compared to only 58 in 2004. Economists have pointed to a policy change in the Medicare Modernization Act that took effect in 2005 as a trigger for the shortages we are seeing today. Though well intentioned, the change has made it impossible for manufacturers to adjust to market forces.

Facing miniscule or negative profits in addition to requirements to provide discounts and rebates for drugs for high-need populations, many manufacturers choose to abandon the production of sterile injectables in favor of a more lucrative market. Additionally, because of the high front-end costs for highly complex infrastructure required for injectable drugs combined with low returns, there is little incentive for new manufacturers to enter a market in a time of shortage.

The *Patient Access to Drugs in Shortages Act* will remedy this problem by creating a payment mechanism that would be triggered any time a generic injectable drug is likely to become in short supply. Specifically, this bill will incentivize manufacturers to continue production of generic sterile injectables by:

- Changing the Medicare reimbursement rate for generic sterile injectables with three or fewer active manufacturers from ASP+6% to the Wholesale Acquisition Cost (WAC)
- Exempting generic sterile injectables with three or fewer active manufacturers from Medicaid rebates and 340B discounts
- Offers an exclusion from the PPACA annual fee for any brand company that enters the market to produce a drug that is in short supply

The deadline to be an original cosponsor of the *Patient Access to Drugs in Shortage Act* is **November 16**. For more information, please contact Robb Walton at [Robb.Walton@mail.house.gov](mailto:Robb.Walton@mail.house.gov).