U.S. Rep. Gallagher: Gallagher, Pocan introduce bill to strengthen medical supply chains

Posted on Friday, Mar 25, 2022

>> WisPolitics is now on the State Affairs network. Get custom keyword notifications, bill tracking and all WisPolitics content. Get the app or access via desktop.

WASHINGTON, D.C. — Reps. Mike Gallagher (R-WI) and Mark Pocan (D-WI) introduced the Medical Supply Chain Security Act. This bill would strengthen medical supply chains by giving the U.S. Food and Drug Administration (FDA) the authority to analyze sourcing locations of medical products and help more quickly bring products to market should shortages exist.

“Just two years ago, the Chinese Communist Party threatened to withhold lifesaving medical equipment from the U.S. so they could drown Americans in a ‘sea of coronavirus.’ If we don’t do everything in our power to end our over-reliance on China for these critical products, next time, these threats could become a reality,” said Rep. Gallagher. “This bill helps address this public health and national security threat by giving the FDA the authority to identify potential bottlenecks in medical supply chains and, if necessary, expedite approval for other products. This is a common-sense, bipartisan solution that will better protect Americans access to critical medicines and supplies.”

Rep. Mark Pocan said, “We need this legislation because currently no law exists requiring medical device manufacturers to notify the FDA when they become aware of a potential shortages or even requiring them to respond to the FDA’s requests for information about the medical device supply chain. Due to our dependence on foreign manufacturing, we need to better understand the threat that supply chain shortages for life-saving medical devices have on patients in America, and we must ensure our government is able to prepare accordingly.”

The Medical Supply Chain Security Act would:

- Require that manufacturers report imminent or forecasted shortages of life-saving or life-sustaining medical devices to the FDA just as they currently do for pharmaceutical drugs. This new information on devices would be added to

the FDA's annual report to Congress on drug shortages.
- Allow the FDA to expedite the review of essential medical devices that require pre-market approval in the event of an expected shortage reported by a manufacturer.
- Give new authority to the FDA to request information from manufacturers of essential drugs or devices regarding all aspects of their manufacturing capacity, including sourcing of component parts, sourcing of active pharmaceutical ingredients, use of any scarce raw materials, and any other details the FDA deems relevant to assess the security of the U.S. medical product supply chain.

Click HERE for bill text.
Background:
Currently, public health officials have limited ability to accurately measure and assess the vulnerability of our medical supply chain. In its Congressional Budget Justification for fiscal year 2021, the FDA asked Congress for more statutory authority to require that manufacturers of medical devices notify the FDA when they become aware of circumstances that may lead to the shortage of an essential medical device. Such information would allow the FDA to ensure that they can take appropriate steps to mitigate potential shortages of life-saving and life-sustaining medical products.
This bill will give the FDA this authority so that they and Congress can take action to protect access to vital medical products in the United States. These reporting requirements will also help reveal the degree to which our medical product industry is reliant on Chinese production and uncover exactly how vulnerable our medical supply chain really is.