JOSH HAWLEY
U.S. SENATOR FOR MISSOURI

Medical Supply Chain Security Act

Background

The spread of the novel coronavirus in China has highlighted severe, longstanding, and unresolved vulnerabilities in the U.S. medical product supply chain. Slowing production at Chinese factories is impacting the supply of key components for pharmaceutical drugs and medical devices produced in the United States, threatening shortages of essential medical products. On February 23rd, Axios reported that the recent outbreak of novel coronavirus has threatened the domestic supply of some 150 pharmaceutical drugs, including antibiotics, generics, and branded drugs. Some of these drugs do not have alternatives in the market. This follows reports of widespread shortages of surgical masks and other personal protective equipment.

Currently, the ability of our public health officials to accurately measure and assess the vulnerability of our medical supply chain is limited. 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 and more. Our public health officials must be privy to the details of the manufacturing capacity of producers of essential drugs and medical devices so that they and Congress can take the necessary action to protect access to vital medical products in the United States. Stronger reporting requirements will 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.

What Senator Hawley's bill does

The *Medical Supply Chain Security Act* will:

- 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.