

# THE DEA CLEARINGHOUSE ACT OF 2018

*Senator Gardner and Senator Coons*

## **BACKGROUND:**

As Congress works to address the opioid crisis, identifying and preventing prescription drug diversion is an essential piece of the puzzle. Unfortunately, bad actors in the pharmaceutical supply chain across the country have discovered how to exploit a major blind spot by purchasing prescription opioids from multiple suppliers. Suppliers, such as pharmaceutical manufacturers and distributors, monitor and assess controlled substance orders before shipment. However, distributors currently lack any visibility into the total volume of opioids their customers purchase from other suppliers, severely hindering their ability to make fully informed assessments of an order that could potentially be suspicious.

Under current law, manufacturers and distributors of controlled substances report controlled substance transaction data to the Drug Enforcement Administration (DEA) using Automated Reports and Consolidated Ordering System (ARCOS). While investigators at DEA analyze these records to identify whether potential enforcement action is warranted, ARCOS data is untimely and incomplete. This is because applicable regulations do not require the data to be reported until months after the drugs have been shipped and potentially diverted and current regulations do not require reports for all controlled substances.

This means that no law enforcement agency or private party has the ability to provide real-time, nationwide oversight of all orders for controlled substances, which is a major contributing factor to disproportionate prescription opioid shipments to certain pharmacies across the country.

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## **SOLUTION:**

Congress must work to ensure manufacturers and distributors have the tools they need to identify drug diversion in real time before it has the ability to inflict damage in our communities.

The DEA Clearinghouse Act of 2018 is a step in the right direction; it eliminates the blind spot exploited by bad actors, guards against prescription drug diversion, and protects the integrity of the supply chain. This legislation requires DEA to contract with a data analytics company to establish a national clearinghouse for all orders of controlled substances and requires that all controlled substance orders pass through this clearinghouse. The DEA clearinghouse will detect potentially suspicious orders using algorithms that reflect DEA's complete visibility into the market and will notify the registrant with whom the order is placed if a potentially suspicious order is detected. The order will then pass through to the registrant with whom the order was placed for further evaluation.

The clearinghouse establishes real-time order monitoring and supply chain transparency to help stop prescription drug diversion before it occurs. By bolstering suspicious order detection capabilities, this legislation prevents prescription opioids from slipping through blind spots in the supply chain and landing in the wrong hands.

Beyond the benefits to public health and safety, this legislation reduces costs to the pharmaceutical supply chain, DEA and safeguards legitimate patient access to medication.