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US federal law for pharmaceutical drug tracking will follow the supply chain where state laws stop short

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The bipartisan push to lower drug prices in the United States (both Senator Bernie Sanders and President Donald Trump have made the issue a priority) has latched onto importing drugs from Canada, where drug prices are significantly lower than in the U.S.

Several states have already passed legislation allowing some patients to import certain drugs from Canada, including Vermont, Colorado and Florida, but the solution has several flaws and criticisms that might end up derailing the option.

The idea of importing drugs from Canada into the United States fails to consider how the global drug supply chain operates. Drug manufacturers typically produce drugs for the global market and negotiate prices with the leading authority in each market, so drugs sold in Canada are not necessarily manufactured in Canada. If U.S. citizens or organizations were to buy drugs in Canada and ship them to the U.S., drug companies would respond by limiting shipments to Canada, suing in U.S. federal court or perhaps raising prices.

The current debate is about drug prices and states versus the federal government, but the larger issue is supply chain security and compliance.

The Drug Supply Chain Security Act

That larger issue, supply chain compliance, is being addressed by the Drug Supply Chain Security Act (DSCSA), signed into law in 2013 and set to fully go into effect in 2023. The DSCSA establishes a national regulatory system for tracking and tracing drugs, and came about to remedy decades of patchwork regulations and systems created by states to combat counterfeit and unsafe drugs; this act, part of the Drug Quality and Security Act is supposed to clean up the drug supply chain.

The law will be implemented by the U.S. Federal Drug Administration and "regulates transactions between dispensers and pharmacies and also among manufacturers, repackagers, wholesale distributors, third-party logistics providers, and trading partners."

The law accomplishes this by establishing product tracing via a unique identifying number that will help verify where a product was manufactured and by whom. This will allow authorities to trace drugs down to the lot in the event of a recall, and eventually down to the unit, and give consumers much greater transparency into the supply chain between manufacturer and pharmacy. These product identifiers on each package include the product national drug code, serial number, lot number and expiration date in human- and machine-readable form.

The law calls for transparent exchanges of information or "interoperability" between the many components of the supply chain, something pharmaceutical companies have resisted for years. The Food and Drug Administration released guidance, "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information," in an effort to

get the many different organizations that handle a drug before it reaches the consumer to create systems (e.g., blockchain) that can allow for the efficient, secure and traceable exchange of information up and down the supply chain. This requirement went into effect January 2015 for manufacturers, repackagers, and wholesale distributors and July 2015 for dispensers. The guidance document is very short and intentionally vague, in order to force industry players to establish and maintain the most efficient systems as dictated by industry standards and technological capabilities. The guidance states that methods could include, but are not limited to, the use of:

- "paper or electronic versions of invoices;
- "paper versions of packing slips;
- "Electronic Data Interchange (EDI) standards, such as 856 Advance Ship Notice (ASN), which is currently used to provide the receiving entity with advance data on shipments; and
- "EPCIS (Electronic Product Code Information Services), which defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain."

November 2019 is the next big deadline by which U.S. drug wholesalers must deal only in products labeled with DSCSA product identifiers. By November 2020, pharmacies can buy only those products that are encoded with DSCSA-mandated product identifiers. By 2023, all drugs entering the U.S. drug channel must be traceable using a unique product identifier.

For more information, resources and a list of FAQs, check out the Food and Drug Administration site dedicated to the DSCSA.