# Imported Medicines, at What Cost?

Importation Proposals Run Counter to Provisions of the Drug Supply Chain Security Act (DSCSA)

## **UNDER DSCSA (PUBLIC LAW 113-54)**

#### **UNDER IMPORTATION**

#### **Products for U.S. Market**

- Authorized Trading Partner
- Serialized product
- Record-keeping requirements



## **Products for Foreign Markets**

- Not an Authorized Trading Partner
- Incompatible or unavailable serialization
- Lack of transparency in sourcing













## U.S. Standard with 2D Bar Code

- National Drug Code
- Serial number
- Lot number
- Expiration date





– Transaction History?– Transaction Information?– Transaction Statement?



## NO

International Standard for Serialization



#### U.S. Wholesaler

- Authorized Trading Partner
- Increased licensure standards
- Using data for verification
- Record-keeping requirements
- Full unit-level traceability in 2023



## **Certified Foreign Seller**

- Not an Authorized Trading Partner
- Not mandated to provide transaction history, information or statement
- No product identifier compatible with U.S. serialization
- No record-keeping requirements







## **U.S.** Dispenser

- Authorized Trading Partner
- Using data for verification and reporting
- Record-keeping requirements
- Full unit-level traceability in 2023



### **U.S.** Importer

- Wholesaler/dispenser
- Not able to meet DSCSA compliance standards
- Unverifiable purchase history



Safe. Efficient. Secure.



Unsafe. Inefficient.\* Vulnerable.



 $<sup>{\</sup>color{blue}^{*}} When \ considering \ Importation \ Proposals, \ North \ Dakota, \ Maine \ and \ Wyoming \ each \ concluded \ Importation \ to \ be \ inefficient.$ 

Visit www.hda.org/importation for more information.

