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

















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





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.



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