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Drug Supply Chain Security Act

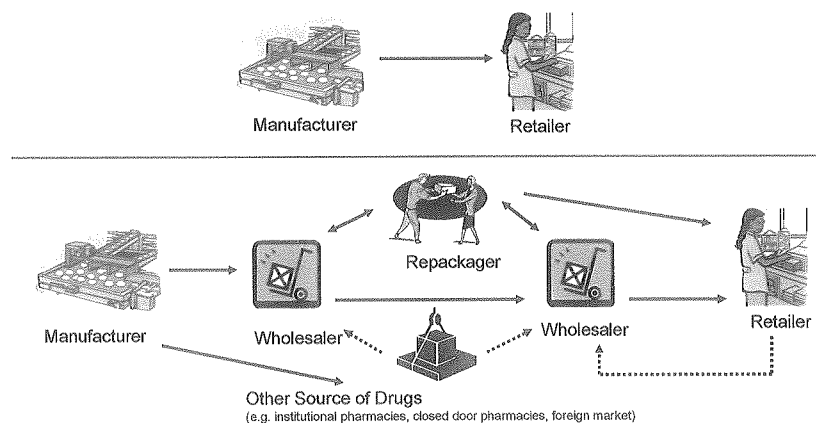
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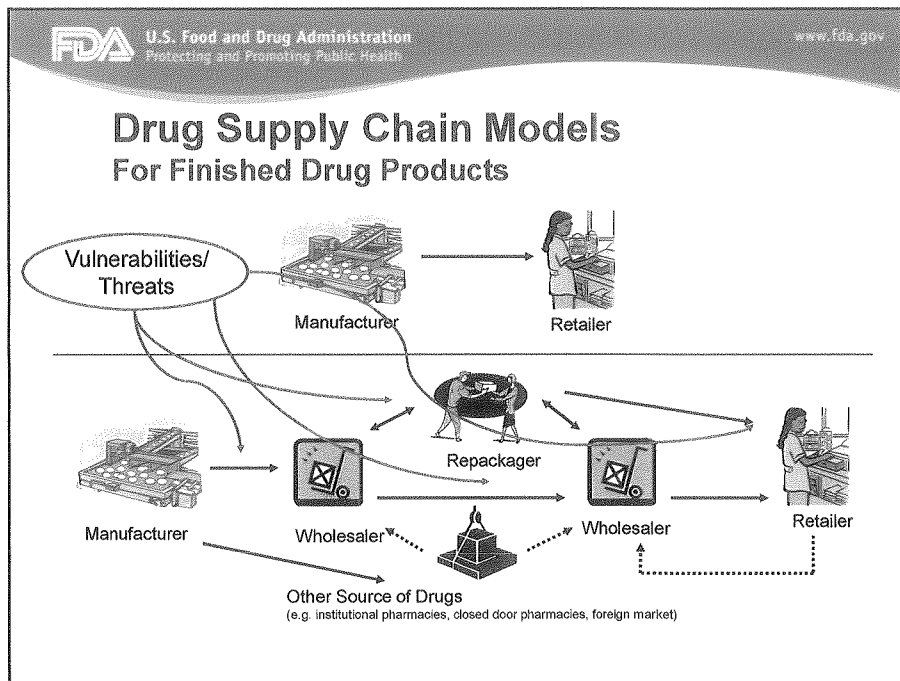


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Drug Supply Chain Models for Finished Drug Products





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Elements of the new law

- Product identification
- Product tracing
- Product verification
- Detection and response
- Notification
- Wholesaler (WDD) licensing/standards
- Third-party logistics provider licensing/standards
- Enhanced system – 10 years
- Penalties
- National uniform policy

4



Product identification

- At four years, manufacturers, followed by repackagers to put a unique product identifier on certain prescription drug packages
 - For example, using a bar code that can be easily read electronically
- Product identifier
 - National Drug Code
 - Serial number
 - Lot number
 - Expiration date
- After six years, wholesalers, followed by dispensers, will trade only products with product identifiers

5



Product tracing

- Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market
- FDA to establish standards for the exchange of transaction documentation that consists of:
 - Transaction *information*
 - Transaction *history*
 - Transaction *statement*

6



Product verification

- Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages in response to requests from wholesale distributors and dispensers

7



Detection and response

- Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous

8



Notification

- Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found

9



Wholesaler licensing and standards

- FDA to develop new federal standards for licensing of wholesale drug distributors and a federal system for wholesale drug distributor licensing for use when a state system does not meet federal standards.
- Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.

10



Third-party logistics provider (3PL) licensing

- 3PLs, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.
- 3PLs to report their licensing status and contact information to FDA.

11



Enhanced system – 10 years

- Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect ten years after enactment of this Act, including those relating to:
 - Electronic exchange of transaction information for each sale of certain prescription drugs
 - Verification of product identifiers at the package level
 - Prompt response to suspect and illegitimate products when found
 - Improved efficiency of recalls

12



Uniform national standards – preemption

- Product tracing and other requirements:
 - No State or local government may establish or continue in effect requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements under 503(e) (as amended by such Act) or the subchapter, or which are inconsistent with any waiver, exception, exemption, or restrictions under sections 581 or 582.
- Wholesale distribution and 3PL standards:
 - Prohibits any state or local government from establishing or continuing any standards, requirements, or regulations with respect to the licensing of wholesale prescription drug distributors or third-party logistics providers that are inconsistent with, less stringent, directly related to, or covered by standards and requirements applicable under section 503(e) (as amended by such Act) or section 584 (for 3PLs)

13



Implementation

- Requires FDA to develop standards, guidances, regulations, pilot programs, and licensing programs and hold public meetings and other efforts to support efficient and effective implementation of the law.

14