U.S. FOOD & DRUG ADMINISTRATION

U.S. FDA Update

The Drug Supply Chain Security Act (DSCSA)

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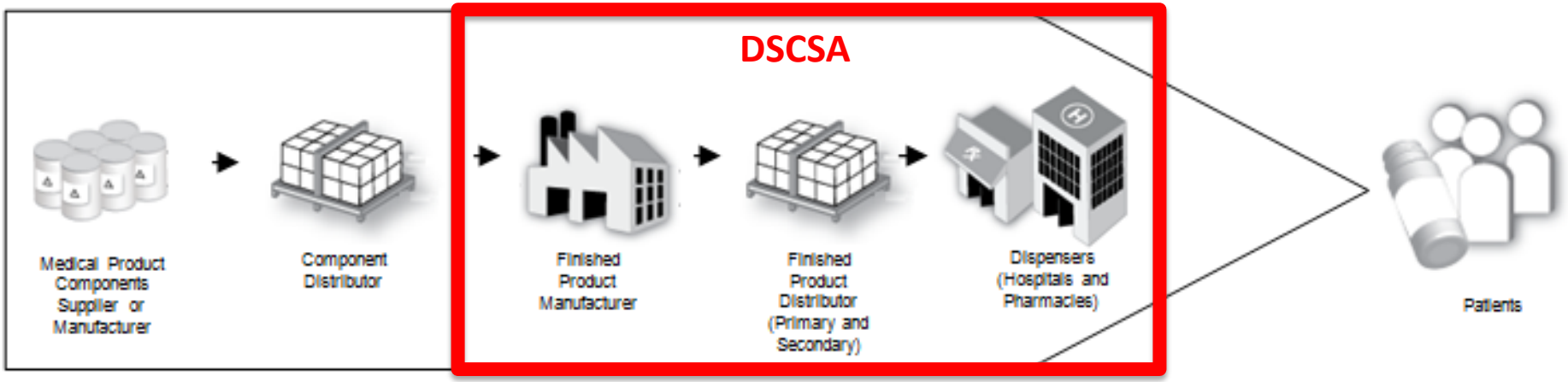
Disclaimer

The content here is intended only to provide a summary and general overview. It is not intended to be comprehensive nor does it constitute legal advice.

Additional Resources

Updates and links to FDA documents or notices summarized in this presentation can be found on the DSCSA webpage on FDA's website.

Pharmaceutical Supply Chain



Maintaining integrity from manufacturer to patient(s)

- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?

Protect the product → **Protect the patient**

Goals of the DSCSA

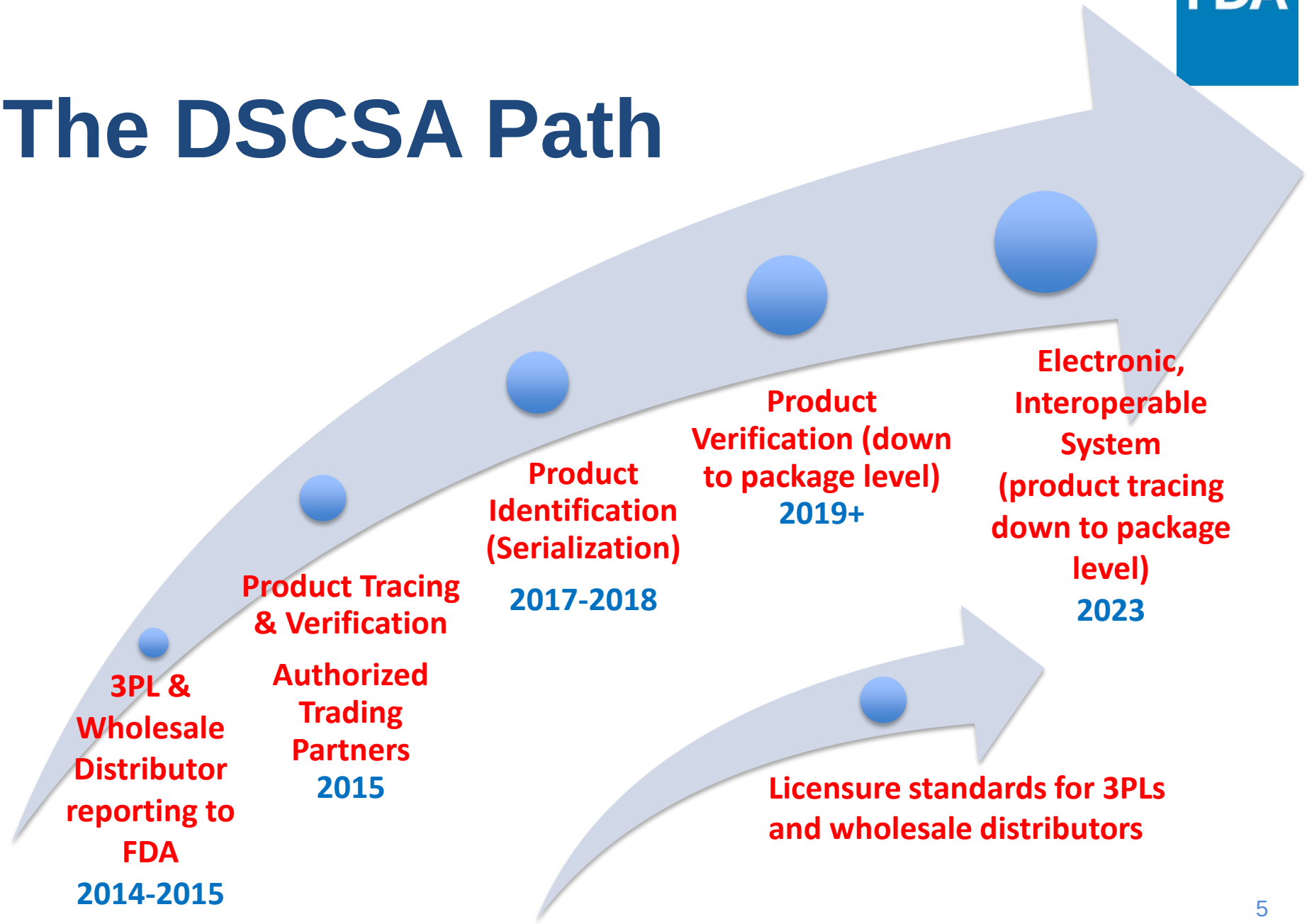
- Develop an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they move through the U.S. supply chain.

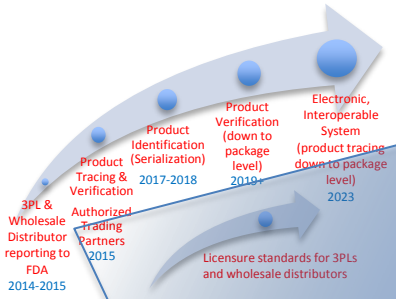
  The new system will:

  - facilitate the exchange of information by trading partners at the individual package level
  - improve efficiency of recalls
  - enable prompt response to suspect and illegitimate products when found
  - create transparency and accountability in the drug supply chain

- Establish national standards for licensure for wholesale distributors and third-party logistics providers.

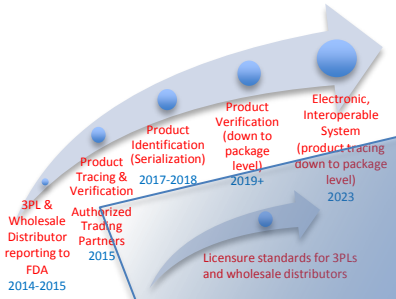
The DSCSA Path





Wholesale Distributor & Third-Party Logistics Provider Reporting Database

- Single national database
- Self reported information by Wholesale Distributors and Third-Party Logistics Providers (3PLs)
- Search capability (by facility name, type, State, or license)
- File download capability



Product Tracing

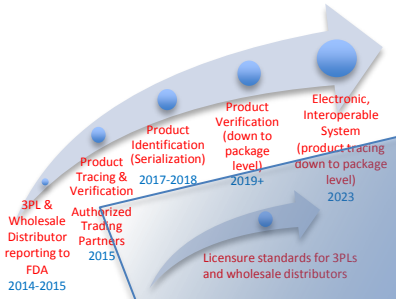
- Trading partners exchange transaction information/history/statement
- Currently, lot-level (package-level by 2023)
- Paper or electronic formats

Verification

- Respond to verification requests for suspect product
- Quarantine & investigate suspect product to determine if illegitimate product
- Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
- Respond to notifications of illegitimate product

Definitions: suspect and illegitimate product

- **Suspect Product** - reason to believe that product potentially:
  - counterfeit, diverted, stolen
  - subject of fraudulent transaction
  - intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans
- **Illegitimate Product** - credible evidence that the product actually is any of the above



Authorized Trading Partners

- Manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers (primarily pharmacies)
- Appropriate registration with or licensure from FDA or State authorities, as applicable

Identifying Trading Partners – Draft Guidance to Industry

- Clarifies the activities of each trading partner under the law and respective requirements
- Seeking public comment until 10/23/2017

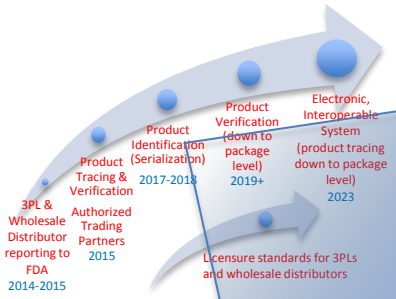
Product Identification (Serialization)

- A unique product identifier must be placed on certain prescription drug packages (in human and machine readable format)
  - Manufacturers (No later than 11/27/2017)
  - Repackagers (No later than 11/27/2018)

- Product identifier consists of
  - National Drug Code
  - Serial number
  - Lot Number
  - Expiration Date

Standardized numerical identifier

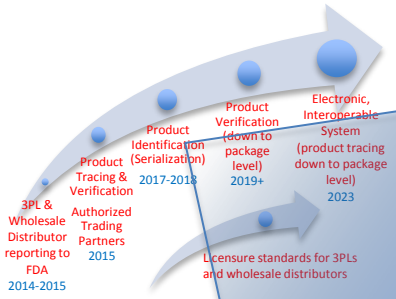
- Data Carrier – 2D data matrix bar code
- Verification requirements change once products are serialized



Public Meeting on Progress Toward Implementing the Product Identification Requirements

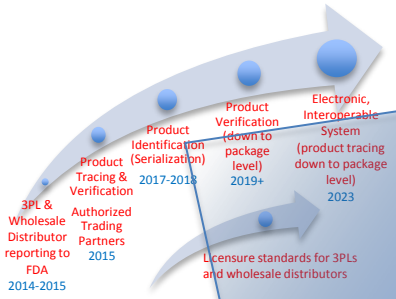
- Industry efforts to implement product identification requirements, including the use of product identifiers to enhance tracing at the package level & verification
- May include aggregation & inference, as necessary
  - Held on October 14, 2016
  - About 150 attendees
  - 10 oral presentations by stakeholders
  - Recorded webcast and slides posted

http://www.fda.gov/Drugs/NewsEvents/ucm519587.htm



Product Identifier Compliance Policy – Draft Guidance to Industry

- One year delay in enforcement of manufacturers requirement to affix or imprint product identifier on package or homogenous case
- Need a product identifier for packages/homogenous cases intended to be introduced into a transaction into commerce on or after November 27, 2018
- Verification : Enforcement discretion for trading partners who do not verify product that was introduced into a transaction into commerce between 11/27/2017 and 11/26/2018 without a product identifier (differs for each trading partner)
  - Public comments are under review



Proposed DSCSA Pilot Project Program

- FDA shall establish 1 or more pilot projects
- Coordinate with manufacturers, repackagers, wholesale distributors and dispensers
- Explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain
- Design: utilization of product identifiers for product tracing and verification, improve technical capabilities needed to utilize product identifiers, identify system attributes that are necessary, other
    - Public comments are under review

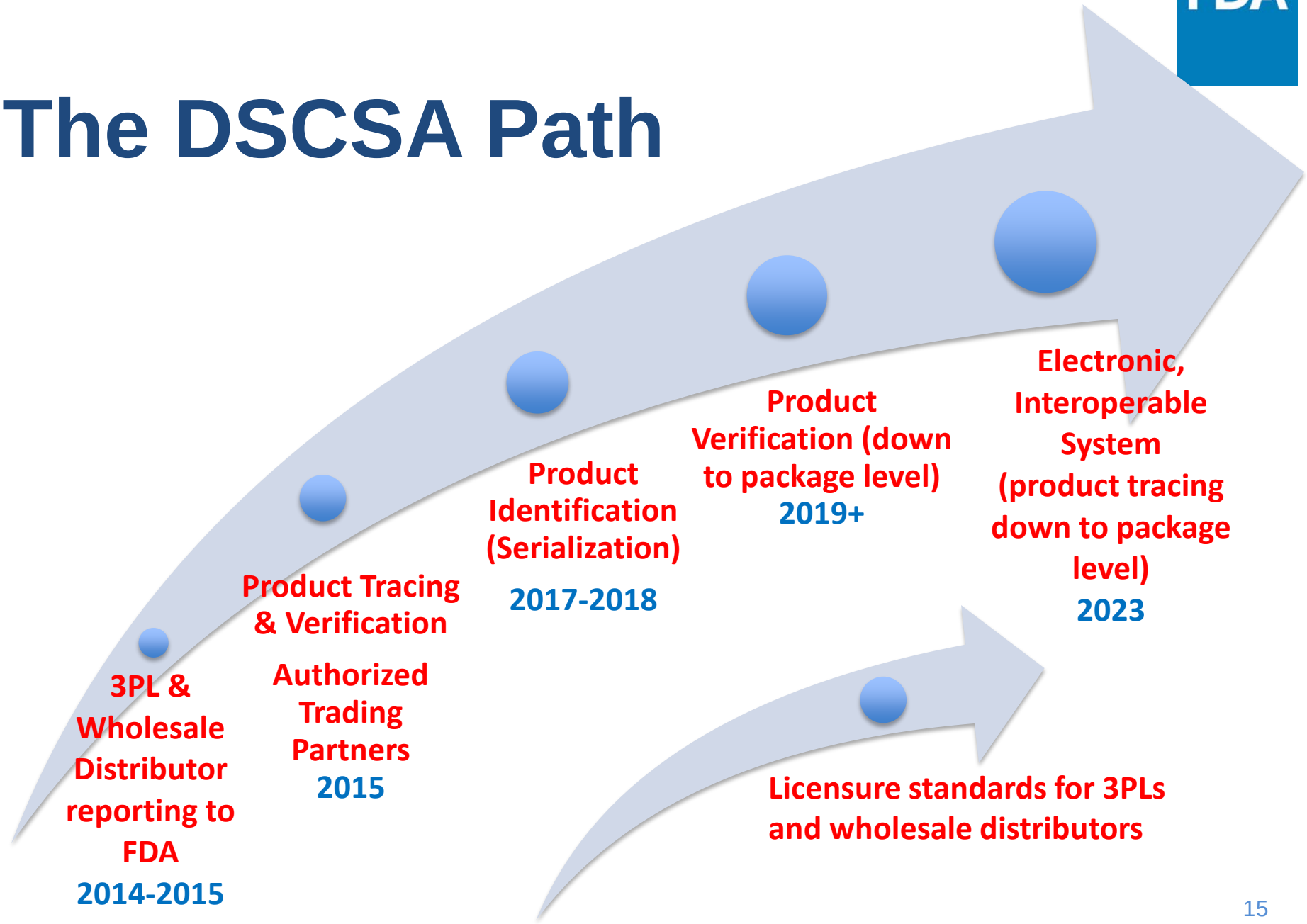
Public Meeting Series

Enhanced Drug Distribution Security Under DSCSA

- Stakeholder input on strategies and issues related to the enhanced drug distribution security provisions of the DSCSA
- 3 public meetings

Dates	Topics
August 23, 2017	• Supply chain security in 2023 • Enhanced drug distribution security needs
December 5-6, 2017	• Electronic interoperability • Standards for data exchange • Data architecture • Aggregation and inference
February 28, 2018	• Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system

The DSCSA Path



Enhanced Drug Distribution Security – 2023

- Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect 10 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

What's Next

- DSCSA Pilot Project Program
- Guidances and Regulations
- Public meetings and other engagement

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THANK YOU!