Collaboration for Global Regulatory Strengthening: Builiding interoperability into regulations

S. Leigh Verbois, PhD
U.S. Food and Drug Administration
Office of International Programs
GS1 Healthcare Conference – Ethiopia
May 2018

Part 1: Why Regulatory System Strengthening Matters to the U.S. FDA

Current State

- Increasing imports
- Limited resources
- Increasing globalization
- Increasingly complex supply chains
- Complex public health outcomes (AMR)

Flip Side

- Tightening supply chains through partnerships
- Leveraging information from capable partners
- Decreasing the global burden of disease

Elements to emphasize in Track and Trace

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.

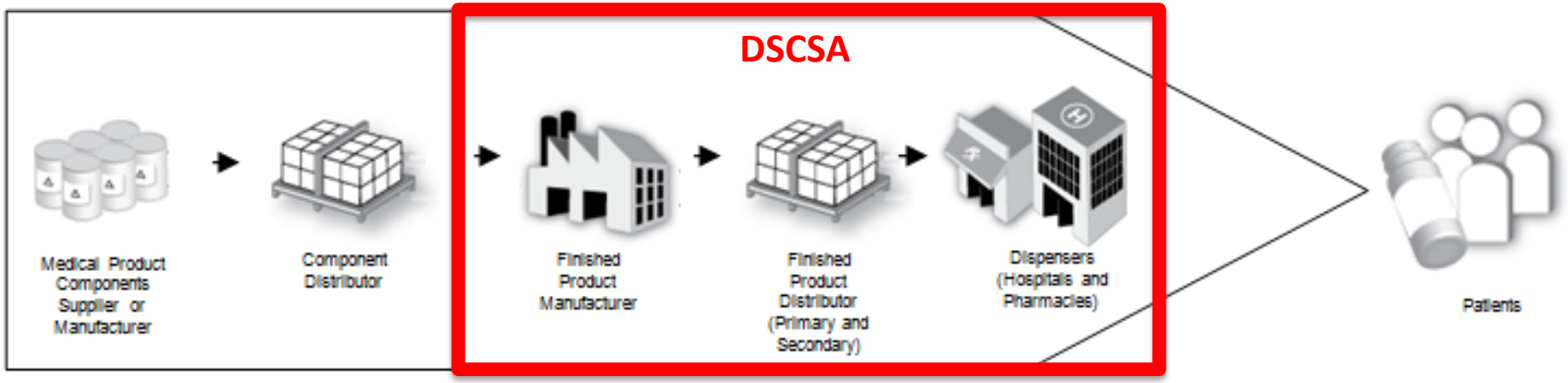
Additional Resources

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

Part 2 Objectives

- Provide an update on implementation of enhanced drug distribution security requirements of the Drug Supply Chain Security Act (DSCSA) in the U.S.
- Describe recent stakeholder engagement through our public meeting series
- Describe plan for engaging and educating stakeholders

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

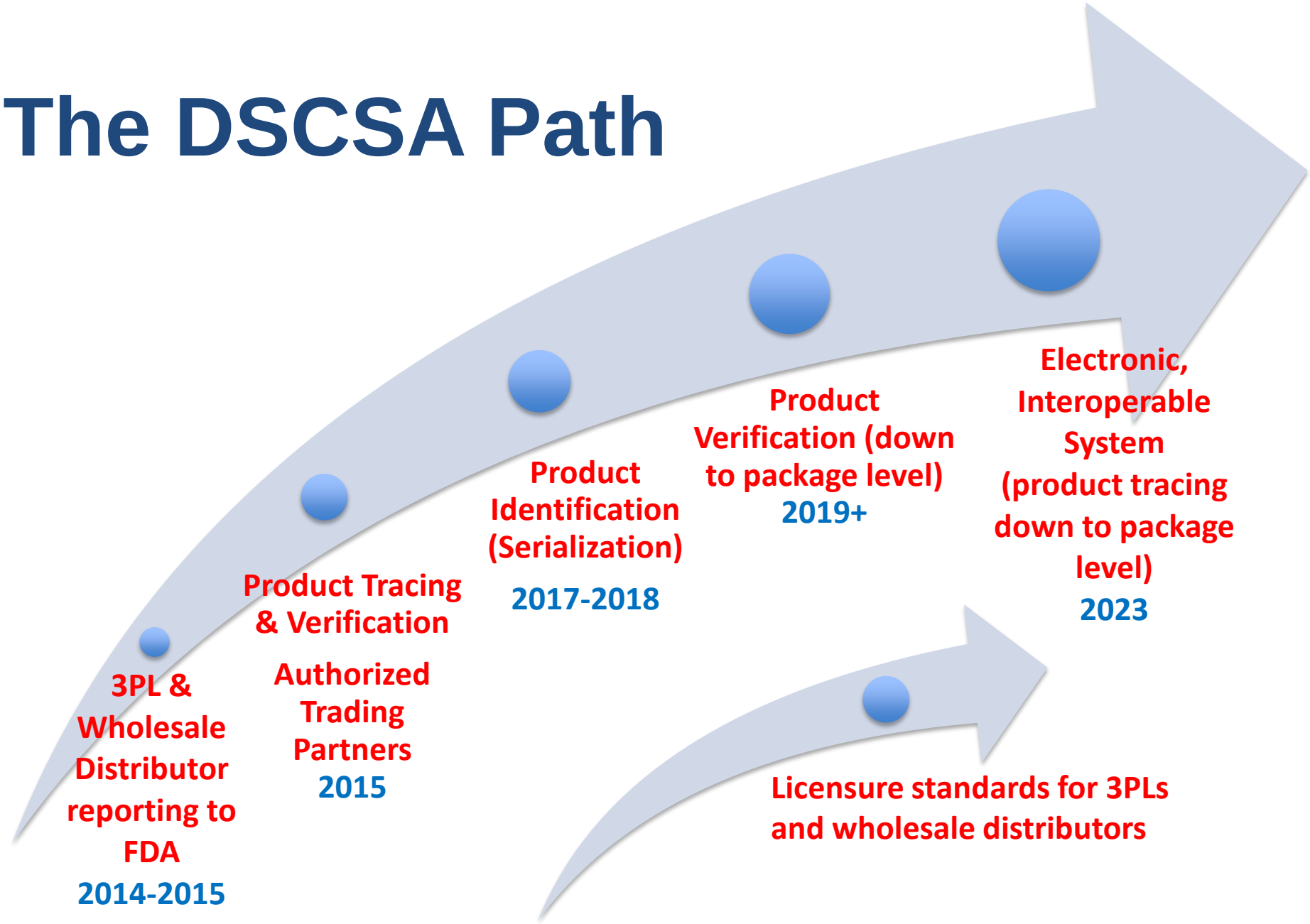
- Develop an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they move through the U.S. supply chain.

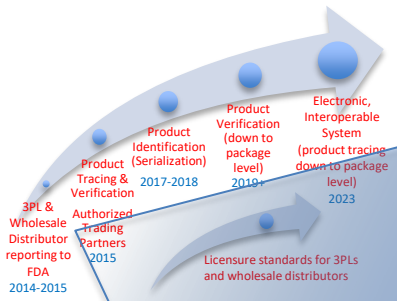
  The new system will:

  - 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.

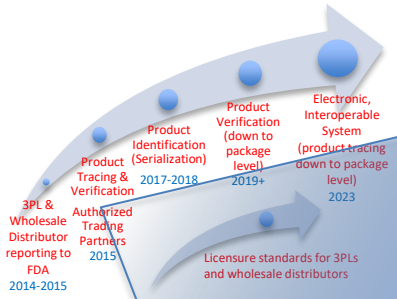
The DSCSA Path





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

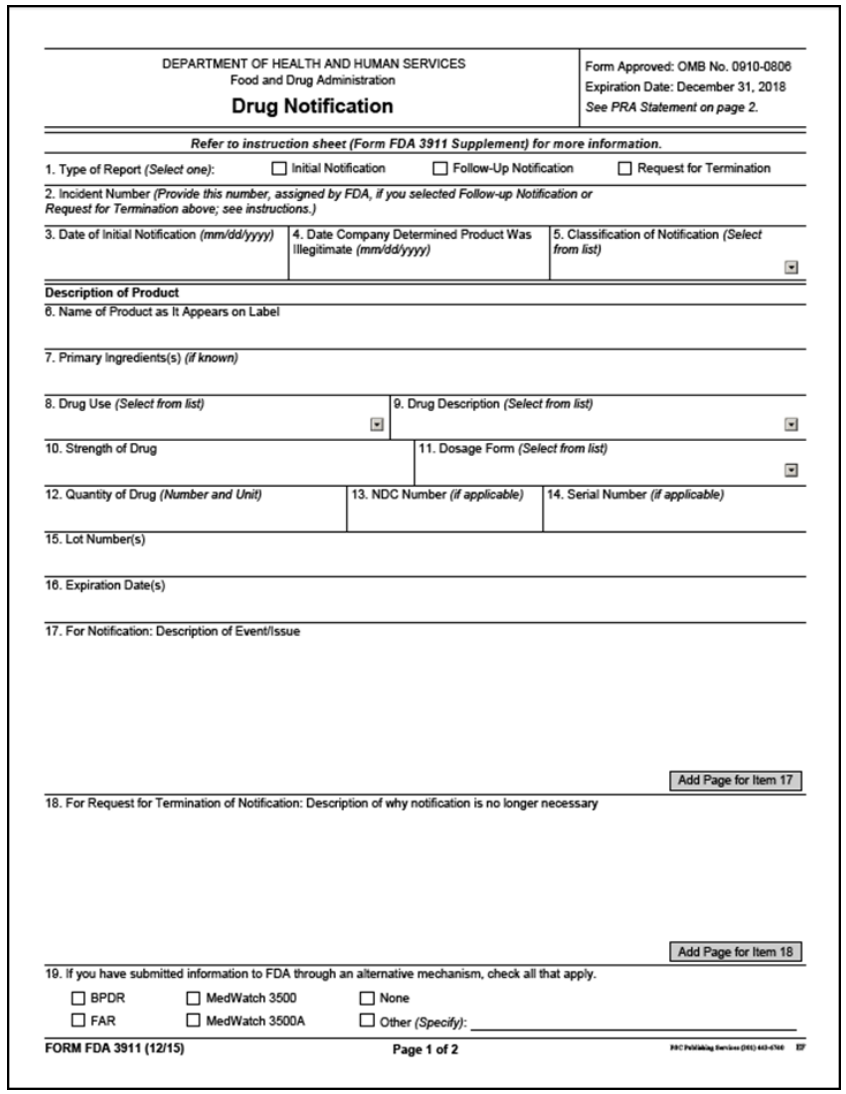
Verification

- 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

Notify FDA of Illegitimate Products



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: December 31, 2018
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification *(mm/dd/yyyy)* | 4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)* | 5. Classification of Notification *(Select from list)*

Description of Product

6. Name of Product as It Appears on Label

7. Primary Ingredients(s) *(if known)*

8. Drug Use *(Select from list)* | 9. Drug Description *(Select from list)*

10. Strength of Drug | 11. Dosage Form *(Select from list)*

12. Quantity of Drug *(Number and Unit)* | 13. NDC Number *(if applicable)* | 14. Serial Number *(if applicable)*

15. Lot Number(s)

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

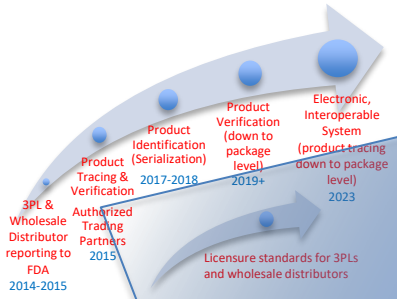
19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

FORM FDA 3911 (12/15) Page 1 of 2

- FDA 3911
- Required to:
  - **Notify FDA of illegitimate product within 24 hours of determination (must also notify other trading partners**).
  - Consult with FDA that a notification is no longer necessary to request termination of notification.
- Who must notify?:
  - Dispensers (primarily pharmacies)
  - Manufacturers
  - Repackagers
  - Wholesale distributors

http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm



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
- Reviewing public comments for finalization

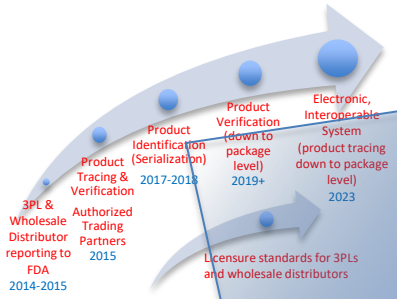
Product Identification (Serialization)

- 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

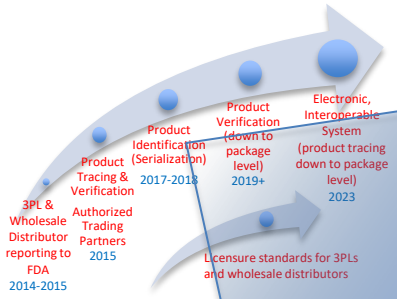
Standardized numerical identifier

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



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 --> 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)
  - Reviewing public comments for finalization



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

Pilot Project Program

Potential Issues to Examine

2018

- FDA intends to initiate the DSCSA pilot project program this year
- Announcement will be published in the Federal Register

Public Meeting Series

Enhanced Drug Distribution Security Under DSCSA

Goal: Gain stakeholder input on strategies and issues related to the enhanced drug distribution security provisions of the DSCSA

DSCSA 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

Recap of DSCSA Public Meetings

August 2017

- **Vision for 2023**
- **Enhanced drug distribution security needs**
- **Roles** of supply chain and FDA
- **Opportunities for interoperability**
- **Improving supply chain efficiency & security**

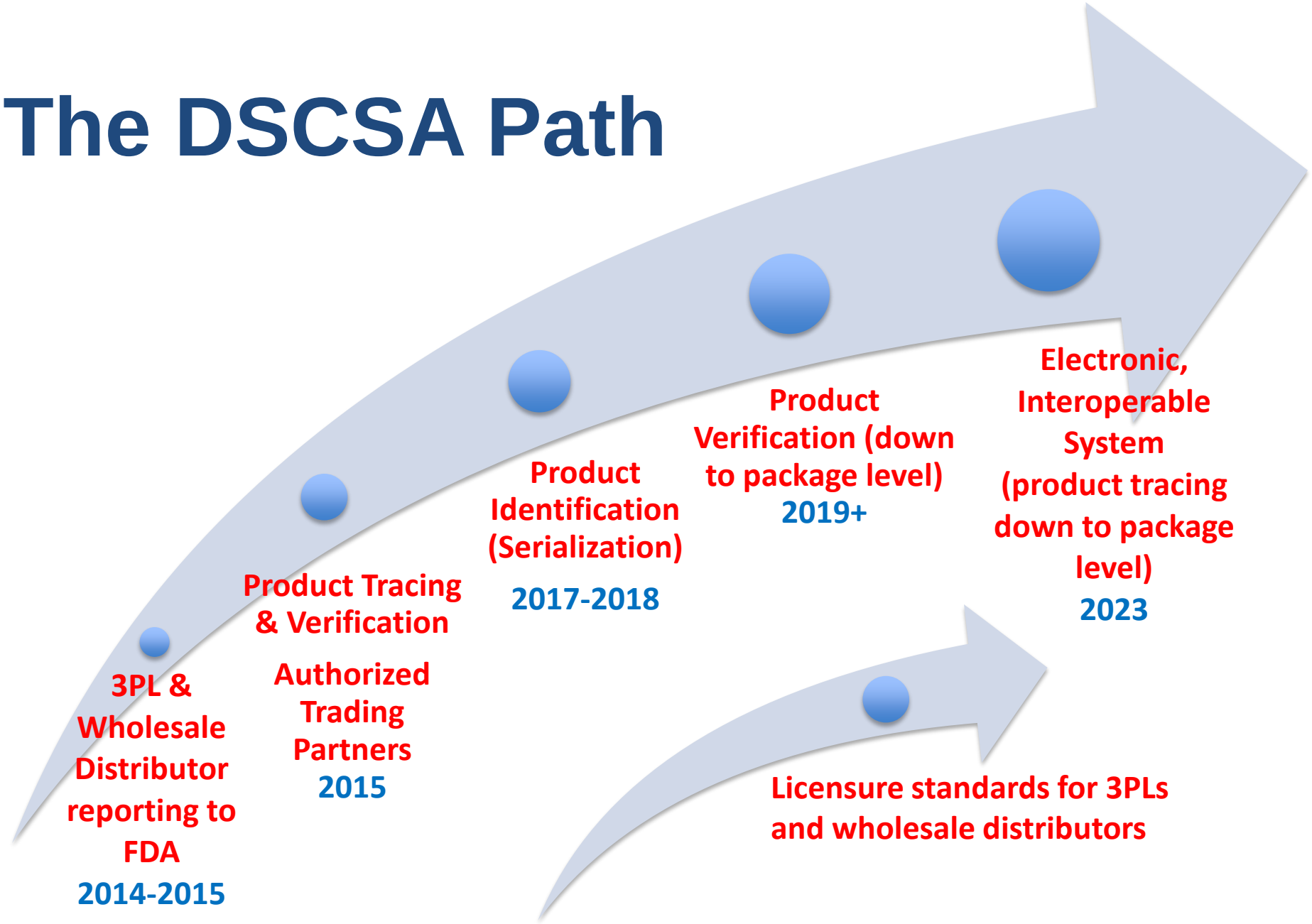
December 2017

- **Standards for data exchange**
- **Data architecture** (distributed model)
- Update on **Falsified Medicines Directive**
- **Aggregation and inference** needs and practices
- **Scenarios**

February 2018

- **Enhanced drug distribution security**
- **Verification** using the product identifier
- **Identified "guardrails"** to assist stakeholders with implementation
- **Prioritized guardrails**

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
- Plan for engaging and educating stakeholders
  - Present and attend stakeholder meetings
  - Targeted communications to trading partners
  - Improvements to info on website
  - Potential public meetings in the future

End Goal

- Transparency
- Security
- Convergence
- Efficiency
- **Public Health**

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ADMINISTRATION

THANK YOU!