THE DRUG SUPPLY CHAIN SECURITY ACT (DSCSA): PRIOR WORK AND FUTURE DIRECTIONS

THE PHARMACEUTICAL DISTRIBUTION SECURITY ALLIANCE (PDSA)
DSCSA: A BRIEF OVERVIEW

- Rationale
  - Threats to security and patient safety
  - Potential benefit of serialization to improve effectiveness of standard recalls
  - A mixed, inefficient response from the states

- Who’s covered?
  - Manufacturers, repackers, wholesale distributors, 3PLs, and Dispensers
  - Dispensers are both pharmacies and providers; individual HCPs are excluded for the most part

- Scope
  - The traceability requirements generally apply to each “transaction” of a “product”
  - Product: prescription drugs in finished dosage form
  - Transaction: the transfer of product between persons in which change of ownership occurs
- **Nov. 27, 2017**
  - MFRs must pass TI/TH/TS in electronic form.
  - Manufacturers must serialize product.
  - MFRs must have systems and processes to verify product identifiers.

- **Nov. 27, 2018**
  - Repackagers must serialize product.

- **Nov. 27, 2019**
  - Wholesalers must only receive serialized product.
  - Wholesalers must verify saleable returns.

- **Nov. 27, 2020**
  - Dispensers must only receive serialized product.

- **Nov. 27, 2021**
  - Ongoing
    - Industry pilots to inform Phase II.

- **Nov. 27, 2023 (Phase II)**
  - Adoption of interoperable system for electronic, unit-level tracing.

- **Jan. 1, 2015 (Delayed to May 1, 2015)**
  - Must work only with "authorized trading partners."
  - MFRs, WDs, and Repackagers must pass, capture, and maintain TI/TH/TS.
  - Must provide TH/TS/TI to the Secretary and other state and federal officials upon request.
  - Must have systems and processes to investigate, verify, and respond to suspect and illegitimate products.

- **July 1, 2015 (Delayed to Mar. 1, 2016)**
  - Dispensers must pass, capture, and maintain TI/TH/TS.

- **Nov. 27, 2013**
  - DSCSA enacted.
  - State laws immediately preempted.

- **Nov. 27, 2019**
  - Adoption of interoperable system for electronic, unit-level tracing.

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- **Nov. 27, 2023 (Phase II)**
  - Adoption of interoperable system for electronic, unit-level tracing.
DSCSA: ACTIVE PHASE I REQUIREMENTS

- What is exchanged?
  - Transaction Information (TI)
  - Transaction History (TH) – a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product
  - Transaction Statement (TS) – a statement in paper or electronic form, that the entity transferring ownership in a transaction

- Phase 1: For dispensers - July 1, 2015 (delayed to March 1, 2016)
  - Entities must work only with “authorized trading partners”
  - Entities must provide TH/TS/TI to the Secretary and federal officials upon request
  - Entities must capture, and maintain, certain information with respect to each product transaction
  - Entities must have systems and processes to investigate, verify, and respond to suspect and illegitimate products
# FDA IMPLEMENTATION OF DSCSA

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<th>FDA Activity</th>
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<td>Suspect and Illegitimate Product Guidance</td>
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**Bill Enacted:** Nov. 2013  
**Statutory FDA Deadline:** Nov. 2014

**Draft guidance:**  
- Nov. 2014
- Aug. 2014
- Nov. 2015
- Nov. 2017

**Final guidance:**  
- Nov. 2023
- Nov. 2025
- Nov. 2027
Initially convened to address threat of CA pedigree system, PDSA worked closely with Congress, FDA and other stakeholders to propose and pass the DSCSA.

After the DSCSA law was signed on Nov. 27, 2013, PDSA shifted its focus to implementing the new law. Areas of focus have included:

- Preemption
- DSCSA Scope and Definitions
- Grandfathering, Exemption, Exceptions, and Waivers
- Identifying and Reporting Suspect and Illegitimate Products
- Information Exchange Requirements
- Validation, Verification, Serialization and Returns Requirements
PDSA REQUIREMENTS EXERCISE

Best Practices
Operational Know-How and Problem Solving
Intel and Insight Sharing
Broader statutory context
PDSA LETTER RE: DSCSA GUIDANCE AND PROCESS FOR EXCEPTIONS AND GRANDFATHERING
Source: PDSA

PDSA and its members have considered and evaluated what we believe to be the most appropriate approaches to exceptions and grandfathering. PDSA offered these comments and suggestions to FDA to assist the

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PDSA LETTER RE: DSCSA Q&A
Source: PDSA

Since the enactment of the DSCSA, members of PDSA have identified a number of questions that are not clearly answered by the plain language of the DSCSA and creates operational

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PDSA LETTER RE: IMPLEMENTATION OF THE JANUARY 1, 2015 DSCSA REQUIREMENTS
Source: PDSA

Given the interconnected nature of the supply chain, we are encountering a large degree of uncertainty and challenge

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THE DRUG SUPPLY CHAIN SECURITY ACT

UPCOMING REQUIREMENTS – PHASE I AND PHASE II
DSCSA: UPCOMING PHASE I REQUIREMENTS

Four years after enactment (November 27, 2017)

- Manufacturers must begin passing TH/TS/TI in electronic form.
- Manufacturers must begin serializing product.
  - Other trading partners must engage only in transactions involving serialized product.
    - Wholesalers (Nov. 27, 2019)
    - Dispensers (Nov. 27, 2020)
- Manufacturers must have systems and processes to verify the product identifier and SNI of suspect products upon request by a trading partner.
  - Repackagers (Nov. 27, 2018), Wholesalers (Nov. 27, 2019), and Dispensers (Nov. 27, 2020) must incrementally have such systems and processes also.
SERIALIZATION REQUIREMENTS BY SECTOR

2017: Manufacturers
Affix PI/SNI to Products
Verify SNI of Suspect Products
Verify SNI of Saleable Returns
Respond to Requests for Verification

2018: Repackagers
Affix PI/SNI to Products
Verify SNI of Suspect Products
Verify SNI of Saleable Returns
Respond to Requests for Verification

2019: Wholesale Distributors
Only Engage in Transactions with PI/SNI
Verify SNI of Saleable Returns
Associate/Verify TI/TS of Saleable Returns

2020: Dispensers
Only Engage in Transactions with PI/SNI
Verify the PI/SNI of at least 3 packages or 10% of suspect product, whichever is greater, or all packages, if fewer than 3
Ten years after enactment

- Phase II is self-effectuating, but the FDA is required to publish regulations and guidance clarifying the requirements.
- Product identifiers will be utilized to electronically pass the required information.
- Information passed will allow product to be traced at the package level, not just lot.
- Transaction history is replaced with a “one up, one back” data packet.
- Requires systems and processes for package-level verification.
  - Not intended to require authentication of each package.
  - May require use of aggregation and inference.
- Entities must associate TI and TS for saleable returns.
CURRENT PDSA WORK PRODUCT

PHASE II: MIGRATION TO INTEROPERABLE SYSTEM FOR ELECTRONIC UNIT LEVEL TRACING
PDSA: MIGRATION WORK STREAM

- Develop processes, models, and systems

PDSA Statutory and Business Viability Evaluation

PDSA Consensus Recommendation(s)

Government
- FDA Policy
- FDA Guidance
- Congressional Ask, if necessary

Industry
- Propose additional industry pilots
- Propose industry evaluation and adoption

Possible PDSA 4Q16 and 1Q17 Activities
Objectives:

1. Identify, describe, and document multiple alternative models or systems that could be used to satisfy the statutory requirements in Phase II (2023) of the DSCSA.
   - “Model” means the structure/location of the data repositories—where the data resides, who creates the data, and how the data moves. Distributed databases that utilize a hub is one example of a model.
   - “System” means the technological transmission infrastructure and mechanism used to exchange and/or discover information between or among data repositories. EPCIS communication, for example, may be one part of a system.
   - It is assumed that some type of distributed model will be used.

2. Evaluate the pros, cons, and viability of the alternative models and systems identified.

3. Identify specific issues related to Phase II for which PDSA should seek policy positions or guidance from FDA.
SCENARIO 1—WHOLESALER OPENS CASE

Data for each transaction:

- A transaction identifier (e.g., order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date*; name/address of seller; name/address of buyer
- Parent-child data (i.e., SNIs)
- Transaction statement

Assumptions:
- Aggregation is only a mechanism to enable inference.
- Parent-child data is moot when the case seal is broken/opened.
- “Cases” are sealed, homogenous cases with security features.
- Business processes identified are not necessarily statutory requirements.
- A 3PL may perform any of the processes on behalf of a MFR, WD, or dispenser, which is then governed by contract.

Mark case not for sale

Scan and capture units

Scan tote and infer units

Match scan against inferred

Capture receive event

Capture receive event

Capture ship event

Capture pack (aggregation) event

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With dispenser capabilities and perspective represented, the supply chain is better able to craft an optimal information exchange model for 2023. To find the best solution, we need dispensers at the table.

By participating in these discussions, dispensers can better align their own business practices with coming supply chain changes—and get a sense of how others are complying.

Coalitions succeed when all stakeholders drive a consensus solution. PDSA continues to be the right forum to represent the full cross-section of industry.

Practically speaking, collaboration with other supply chain participants can facilitate visibility into and partnership opportunities for upcoming pilots.

PDSA provides participants access to the most timely, accurate, and valuable information related to serialization and traceability.
PDSA MEMBER ORGANIZATIONS