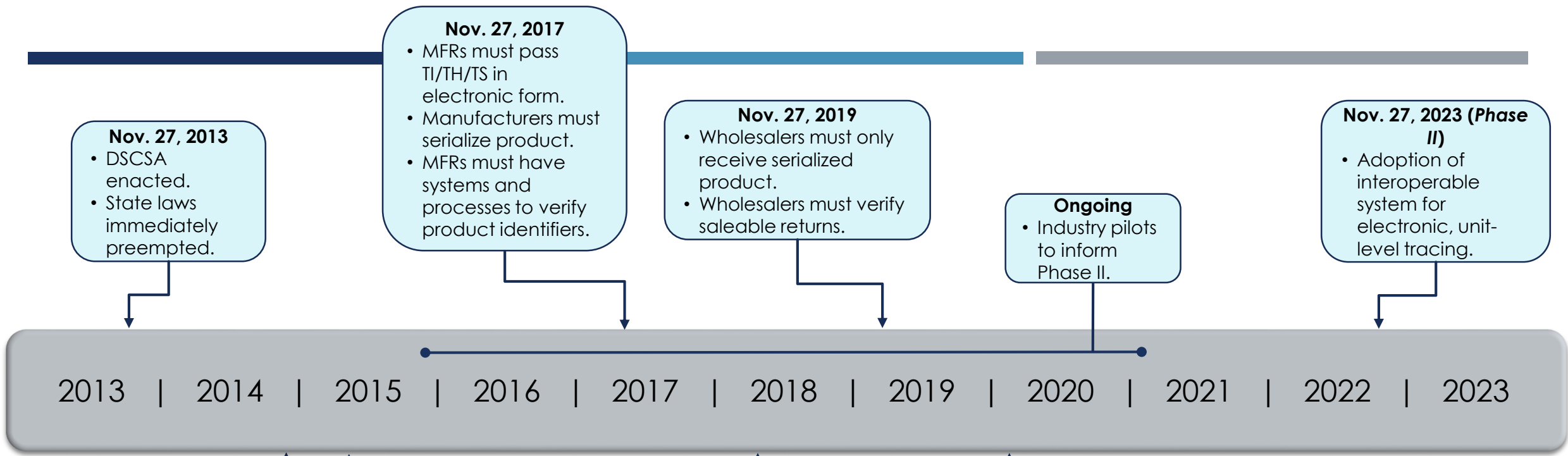# THE DRUG SUPPLY CHAIN SECURITY ACT (DSCSA): PRIOR WORK AND FUTURE DIRECTIONS

THE PHARMACEUTICAL DISTRIBUTION SECURITY ALLIANCE (PDSA)

Anne Marie Polak, Leavitt Partners

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, repackagers, wholesale distributors, 3PLs (licensure), and Dispensers
  - "Dispensers" includes 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, 2013
- DSCSA enacted.
- State laws immediately preempted.

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

Ongoing
- Industry pilots to inform Phase II.

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

2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023

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 TI/TH/TS 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, 2018
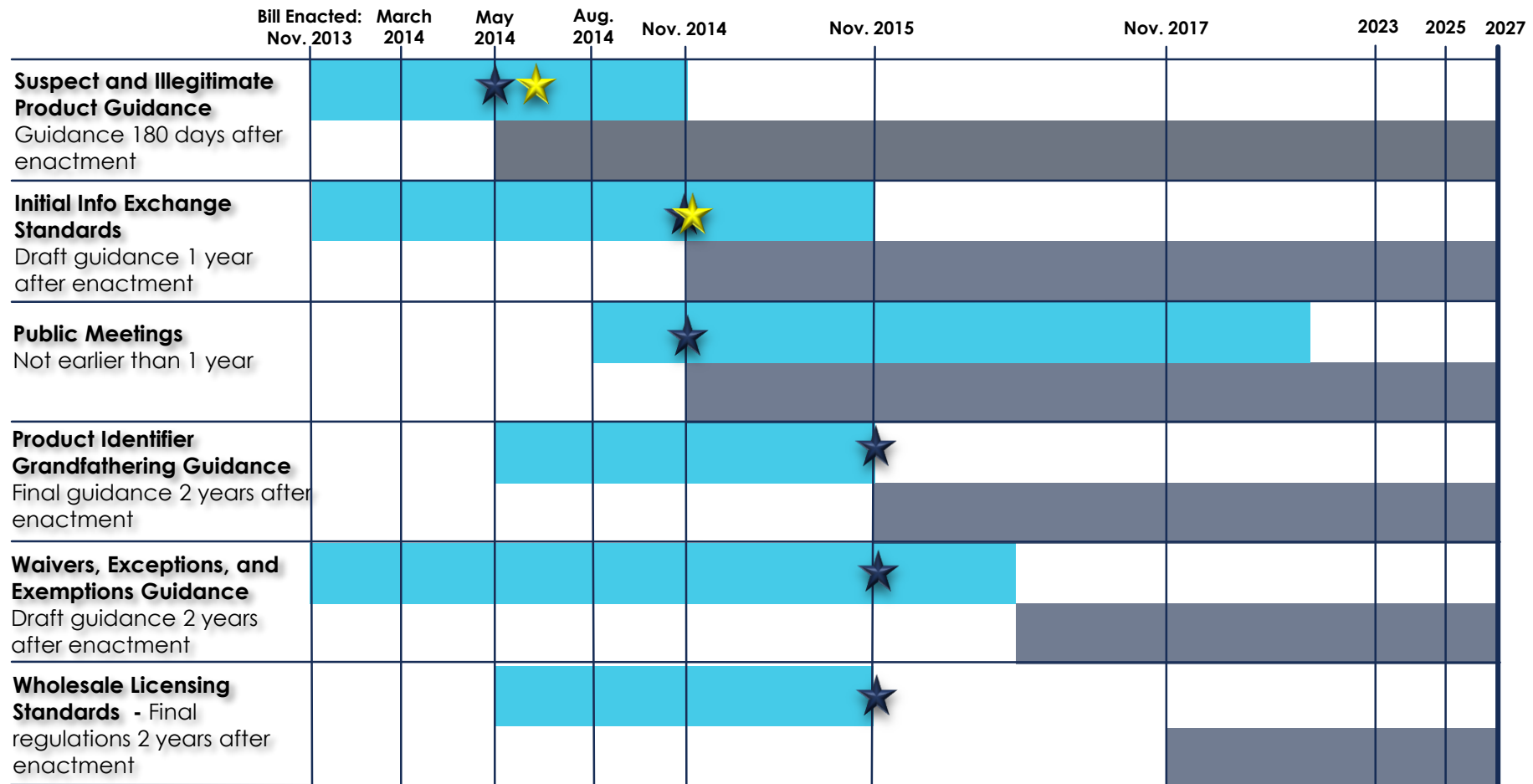- Repackagers must serialize product.

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

DSCSA: ACTIVE PHASE 1 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

	Bill Enacted: Nov. 2013	March 2014	May 2014	Aug. 2014	Nov. 2014	Nov. 2015	Nov. 2017	2023	2025	2027
Suspect and Illegitimate Product Guidance Guidance 180 days after enactment			★ ⭐							
Initial Info Exchange Standards Draft guidance 1 year after enactment					⭐					
Public Meetings Not earlier than 1 year					★					
Product Identifier Grandfathering Guidance Final guidance 2 years after enactment						★				
Waivers, Exceptions, and Exemptions Guidance Draft guidance 2 years after enactment						★				
Wholesale Licensing Standards - Final regulations 2 years after enactment						★				

⭐ Guidance Document Issued ★ Statutory FDA Deadline FDA Activity Industry Implementation/Compliance

THE PHARMACEUTICAL DISTRIBUTION SECURITY ALLIANCE

PAST WORK PRODUCT – DSCSA PHASE 1

EVOLUTION OF PDSA

- 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 WEBSITE: FDA SUBMISSIONS & OTHER DSCSA RESOURCES

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...

Read More →

📅 June 8, 2015   ☰ PDSA

PDSA LETTER RE: DSCSA GUIDANCE AND PROCESS FOR EXEMPTIONS AND WAIVERS

Source: PDSA

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

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📅 May 14, 2015   ☰ PDSA

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 create operational...

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📅 May 22, 2014   ☰ PDSA

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 regarding January 1, 2015 implementation across all sectors of the supply chain. As with

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CONTACT US

The PDSA is interested in hearing from you.
Learn More →

pdsaonline.org

THE DRUG SUPPLY CHAIN SECURITY ACT

UPCOMING REQUIREMENTS – PHASE I AND PHASE II

DSCSA: UPCOMING PHASE 1 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 Suspect Product
- 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

DSCSA: PHASE II – 2023 OBLIGATIONS

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.

- 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.

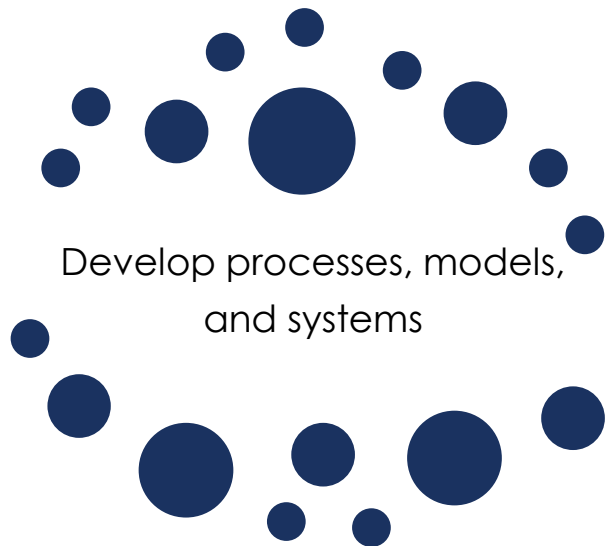- Entities must associate TI and TS for saleable returns.
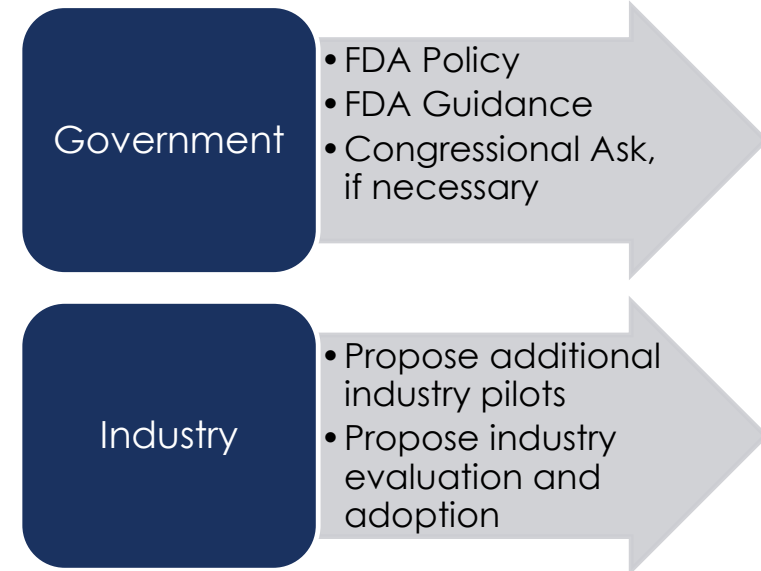
CURRENT PDSA WORK PRODUCT
PHASE II: MIGRATION TO INTEROPERABLE SYSTEM FOR ELECTRONIC UNIT LEVEL TRACING

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

PDSA: MIGRATION PROCESS

- **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.
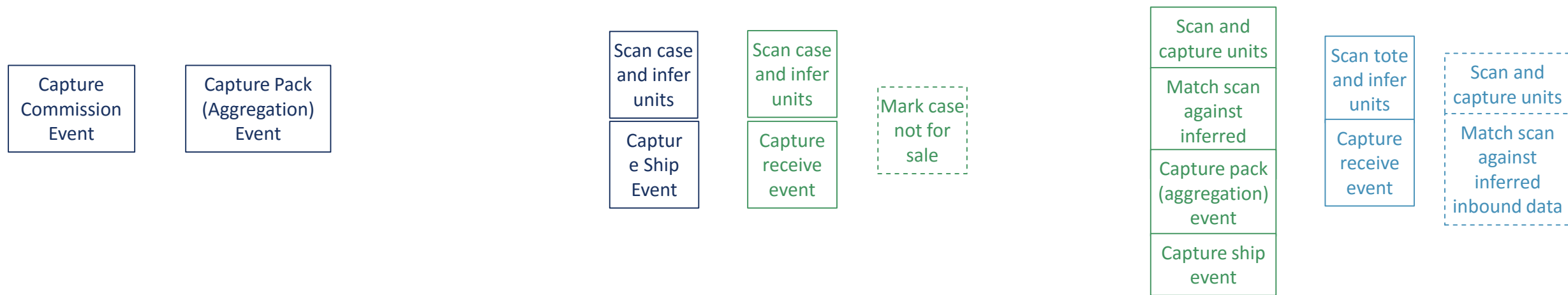
SCENARIO 1—*WHOLESALER OPENS CASE*

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.*

Data Supply Chain

| Capture Commission Event | Capture Pack (Aggregation) Event | | Scan case and infer units / Capture Ship Event | Scan case and infer units / Capture receive event | Mark case not for sale | | Scan and capture units / Match scan against inferred / Capture pack (aggregation) event / Capture ship event | Scan tote and infer units / Capture receive event | Scan and capture units / Match scan against inferred inbound data |

Physical Supply Chain

| Commission SNI | Aggregate to Case | Inventory | Pick | Ship Case | Receive Case | Open Case | Inventory | Pick, pack, ship | Receive Units | Inventory |

Manufacturer   Wholesaler   Pharmacy

PDSA: VITAL ROLE AND BENEFIT FOR DISPENSERS

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