Industry Update: Recent Developments and Unanswered Questions Concerning Implementation of the DSCSA

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Panel*

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*The views expressed during this panel are those of the individuals and do not reflect the official policy or position of their respective organizations.

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Topics for Discussion

1. “Authorized” Status
    - Manufacturer Registration
    - Co-licensed partner
    - Licensed HCPs
    - Best practices
2. Suspect/Illegitimate Product Notifications
3. FDA Guidance on Grandfathering
    - “Intended to be introduced into commerce”

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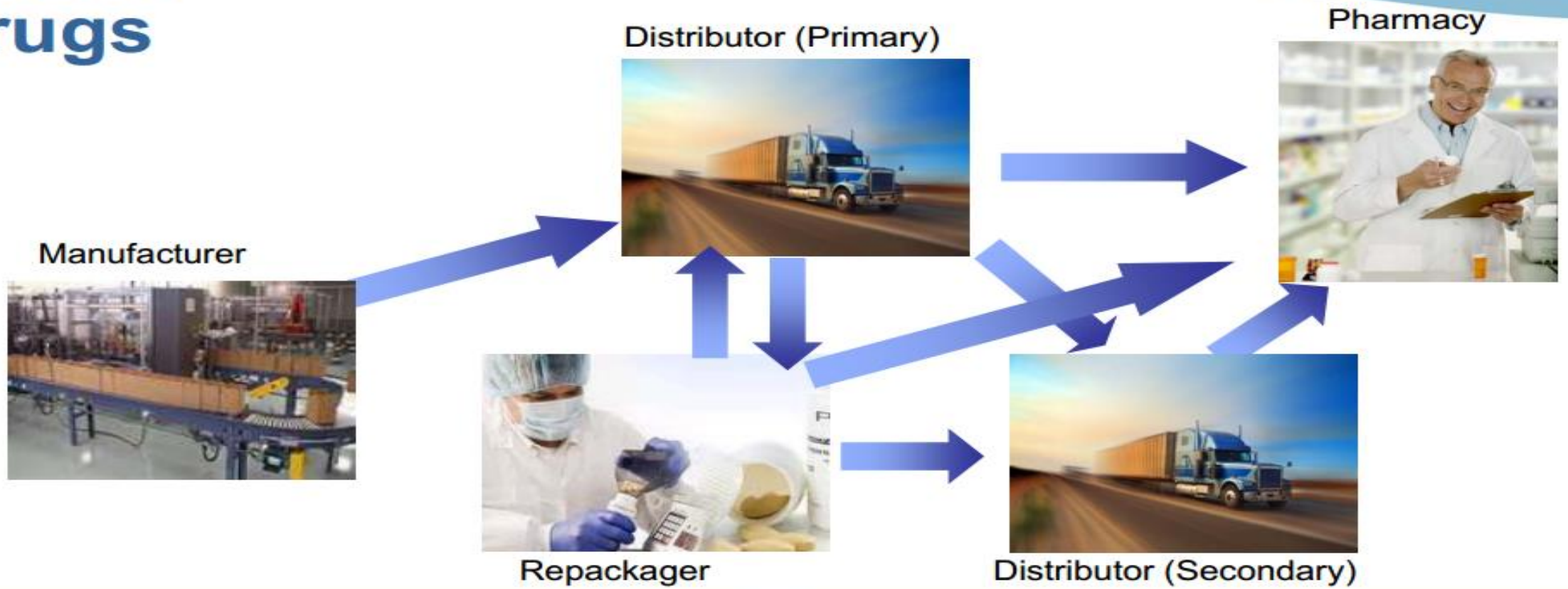
Supply Chain for Finished Drugs



Complexity of the supply chain is increased by:

- Multiple participants
- Globalization of supply chains
- Criminal activities such as diversion, cargo theft, and counterfeiting
- Rules that vary by state

Example of vulnerabilities in the supply chain:

- Stolen products reintroduced
- Counterfeit/falsified drugs sold to suppliers
- Diverted drugs resold
- Other adulterated/misbranded drugs introduced

Where Track and Trace Can Help

Distributor (Primary)

Pharmacy

Stolen Levemir sold to distributors

Manufacturer

Repackager

Distributor (Secondary)

Heparin (recall)

Counterfeit Lipitor

Counterfeit Avastin

Stolen Eli Lilly drugs that may be introduced into the supply chain

Florida pharmacists trying to introduce diverted medicare / medicaid drugs into the supply chain

"Authorized" Status

- The DSCSA requires all parties in the U.S. drug supply chain to be "authorized"
  - **Manufacturer** – registered with FDA
    - Includes NDA, BLA, ANDA Holder
    - Includes co-licensed partner
    - Includes affiliate of manufacturer or co-licensed partner
  - **Repackager** – registered with FDA
  - **Wholesale distributor** – licensed under applicable State law(s) and reporting to FDA
  - **Dispenser** – valid license under State law
  - **Third-party logistics provider (3PL)** – valid license under state law or w/ FDA and reporting to FDA
- May only engage in transactions with "authorized" trading partners
- FDA Draft Guidance:
  - Identifying Trading Partners Under the DSCSA (Aug. 2017)

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Manufacturer: Authorized Status

- Are NDA/BLA/ANDA holders or co-licensed partners who do not engage in manufacturing required to register with FDA?
- When does an affiliate of a manufacturer have to be authorized?
- Do manufacturers have to register as wholesale distributors?
  - E.g., in states where they distribute their own product?
- What address should manufacturers use on DSCSA registrations?
- What are the best practices for manufacturers confirming "authorized" status of downstream customers?
  - Individual HCPs (e.g., product replacement)?

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Manufacturer Authorized Status

- FDA Draft Guidance on Identifying Trading Partners
  - NDA/BLA/ANDA holder or co-licensed partner might not engage in actual manufacturing, but is still a "manufacturer" under the DSCSA
  - Such entity is still "an authorized trading partner without being registered" with FDA "so long as the NDA-, BLA-, or ANDA-holder, or co-licensed partner is compliant with its obligations under section 510" of the FDCA."
  - An affiliate would qualify as a manufacturer under the DSCSA if: (1) the affiliate receives the product directly from such manufacturer; and (2) legal control (direct or indirect) exists between the two (or more) entities (e.g., parent/subsidiary)
  - Manufacturers "only distributing its own drug [] would not be engaged in wholesale distribution under [the] DSCSA, and would not be required to comply with the licensure and reporting requirements for WDDS under DSCSA."

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Dispenser-to-Dispenser Activities

- Can pharmacies or dispensers sell product to other pharmacies under the DSCSA (e.g., increase or replenish stock)?
- What issues do pharmacy-to-pharmacy product transfers raise?
- Do the pharmacies need wholesale distributor licenses?
- Do the pharmacies need to pass and maintain track/trace information?
- How would a manufacturer address a suspect/illegitimate product notification if a pharmacy-to-pharmacy sale occurred?

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Suspect and Illegitimate Product Notifications

- What steps are trading partners taking to obtain product “in their possession” to make illegitimate product determinations?
- How are trading partners implementing the 24-hour illegitimate product notifications?
- How are manufacturers interpreting the “high risk of illegitimacy” notification requirements?
  - What are some “reasons to believe” an immediate trading partner may have illegitimate product?
  - What type of “specific high risk” would increase the likelihood that illegitimate product will enter the U.S. supply chain?
  - What are “other high risks”?
- How have such t notices affected other cGMP, quality issues?
- Any import challenges associated with “high risk”?

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FDA Grandfathering Guidance

- 21 U.S.C. § 360eee-1(a)(5) required FDA by November 27, 2015 to "finalize guidance" specifying when product in the supply chain is exempt from the product identifier requirements.
- No draft, interim or final guidance as of today
- CDER 2017 Guidance Agenda (Sept. 2017)
  - "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier"
  - "Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy"
  - "The Product Identifier for Human, Finished, Prescription Drugs: Question and Answers"
- July 2017
  - FDA issues Compliance Policy providing 1-year grace period for serialization
  - "intended for interstate commerce"

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Open Questions on DSCSA Implementation

- How are trading partners thinking about TI/TH/TS data/documentation standard practices?
- What type of verification systems are trading partners using?
- Has FDA issued any waivers or exceptions to DSCSA requirements?
  - Guidance required by November 2015; no guidance
- What types of fees are trading partners incurring for compliance with the DSCSA?
- Will FDA begin to evaluate, inspect DSCSA compliance within cGMP labeling, packaging requirements?
- Any updates on DSCSA Interoperability for 2023?

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Open Questions on DSCSA Implementation

- FDA 2017 CDER Guidance Agenda
  1. Standardization of Data and Documentation Practices for Product Tracing
  2. Verification Systems Under the DSCSA for Certain Prescription Drugs
  3. Waivers, Exceptions and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act
  4. Fees Incurred Under the DSCSA
- FDA DSCSA Public Meetings
  - Dec. 5-6, 2017: electronic interoperability, standards for data exchange, data architecture, aggregation and inference
  - Feb. 28, 2018: refinement of enhanced distribution security needs and capacity for unit-level system

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Questions?

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