FDA DSCSA UPDATE

(A more innocent time)

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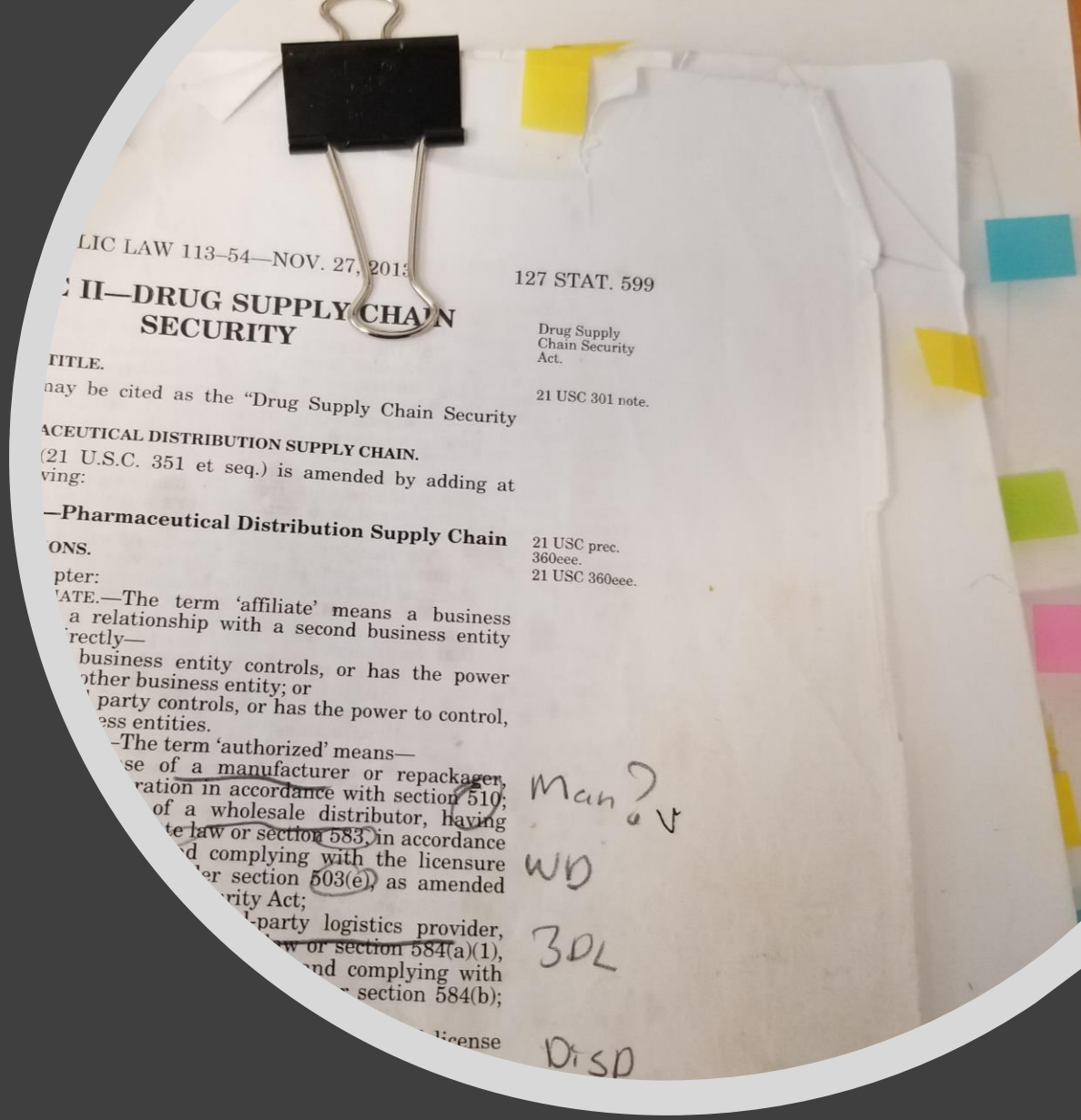
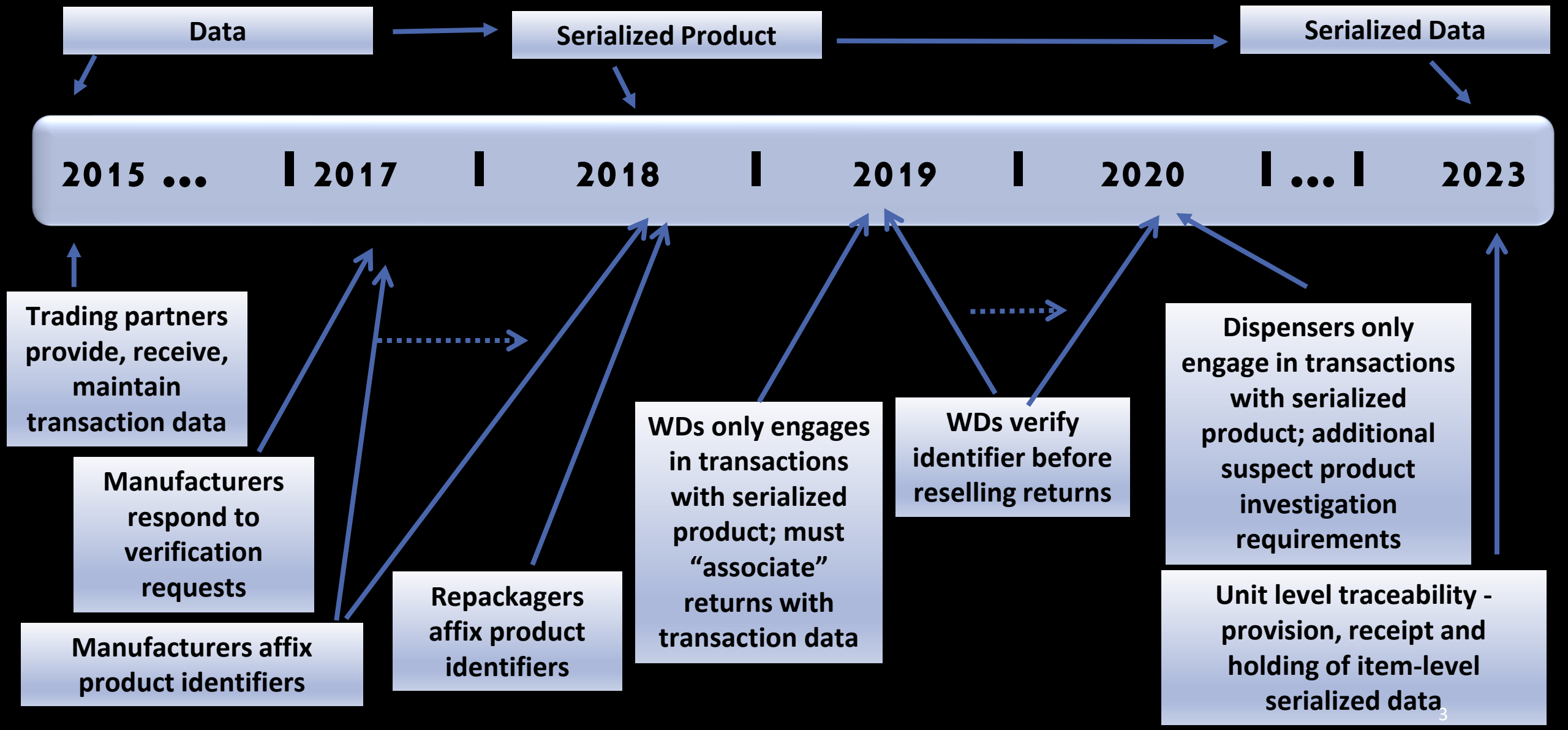
April 14, 2020



Disclaimers

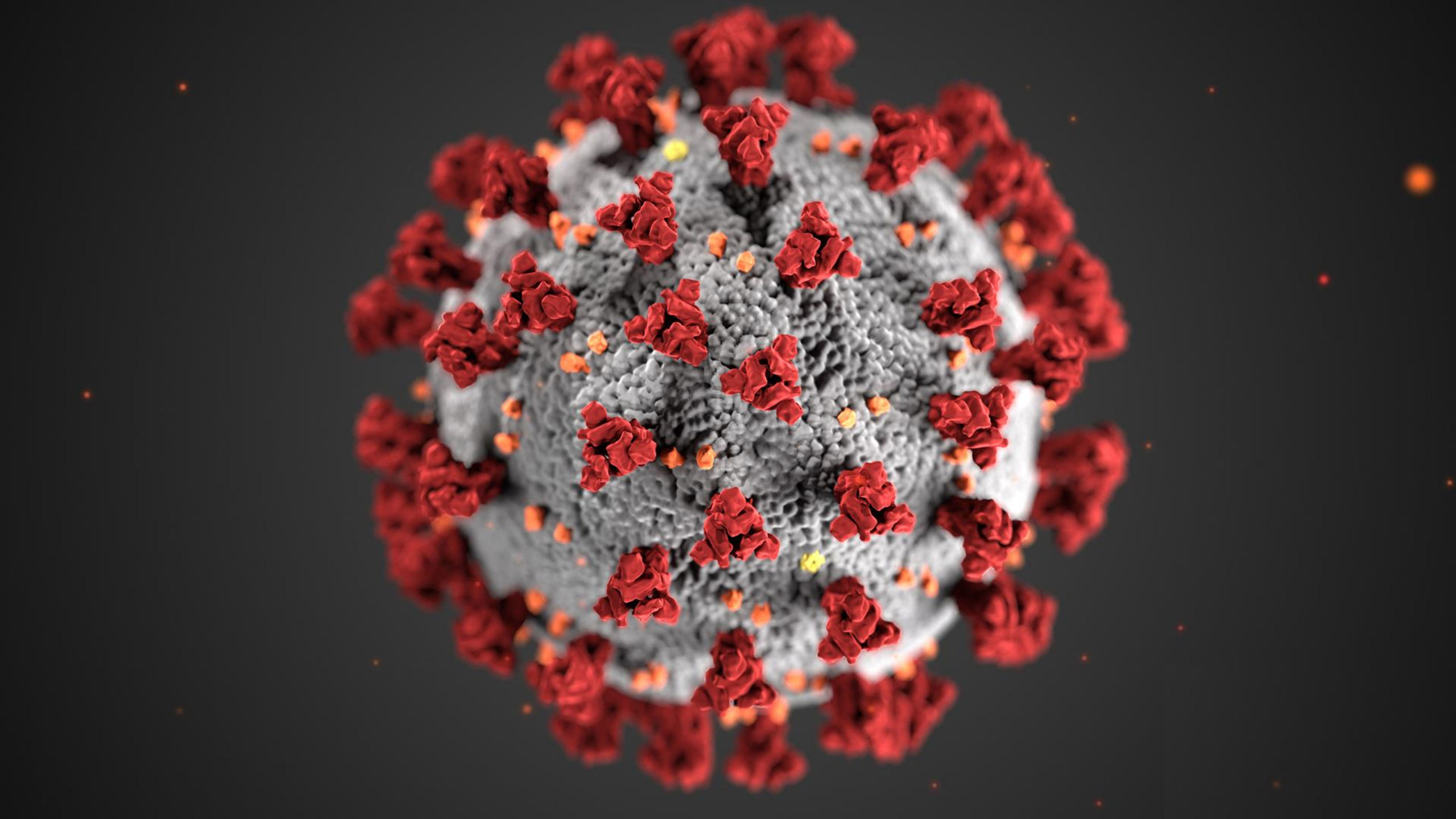
- This presentation is not legal advice.
- This can’t cover everything.
  - Refer to FDA, the DSCSA, and implementing guidances for more information.
  - What is known can change.
    - (Like a global pandemic)
- Other interpretations are possible.

SOME KEY DSCSA MILESTONES



March 2019 - March 2020

- Changes at FDA
- Pilots (Spring 2019)
- Theft reporting (Spring 2019)
- Recalls Draft Guidance (April 2019)
- FDA Listening Session (May 2019)
- Enforcement Discretion for Wholesale Distributor Verification for Saleable Returns (Sept. 2019)
- Importation of unapproved drugs (Dec. 2019)
- Enforcement and inspections
- What's to come in 2020?
- OIG Report



operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(19) Specific patient need

The term ''specific patient need'' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(20) Standardized numerical identifier

The term ''standardized numerical identifier'' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(24) Transaction

(A) In general

The term ''transaction'' means the transfer of product between persons in which a change of ownership occurs.

(B) Exemptions

The term ''transaction'' does not include—

(i) intracompany distribution of any product between members of an affiliate or within a manufacturer;

(ii) the distribution of a product among hospitals or other health care entities that are under common control;

(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 247d of title 42, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 353(b)(1) of this title;

(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 353(d) of this title;

Changes at FDA

- Commissioner changes, Dr. Gottlieb, to Dr. Sharpless, to Dr. Hahn
- Departure of Ilisa Bernstein

Pilot studies

- FDA working with stakeholders to pilot methods to enhance drug supply chain safety and security.
- 20 pilots, https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/dscsa-pilot-project-program

Project Leads	Pilot Project Title
AmerisourceBergen/Xavier Health	AmerisourceBergen Xavier Health End-to-End 2023 Proof of Concept Pilot
Cardinal Health	Interoperability Data Exchange Errors and Exception Handling
Franciscan Missionaries of Our Lady Health System (FMOLHS)	DSCSA Verification to Improve Product Traceability at FMOL Health System
GS1	Barcode Readability for DSCSA 2023 Interoperability
IBM/KPMG/Merck/Walmart	DSCSA Blockchain interoperability Pilot
ICON INDICES	Enterprise Serialization Architecture of Point-To-Point Network System
IDLogiq	IDLogiq Next Generation Advanced REAL FIPS-Compliant Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment
KitCheck	Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies

LSPediA	Router Service Solution for Verification/Notification and Interoperability 2023
MediLedger	MediLedger DSCSA Pilot
Optel	Improved end-to-end drug supply chain traceability with OPTEL's Intelligent Supply ChainTM technologies
The Optimal Solution	The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA
Pharmaceutical Distribution Security Alliance (PDSA)	DSCSA Governance Processes
PriMed Pharmaceuticals	Secondary Wholesaler Challenges During Implementation of DSCSA Required Track & Trace Platforms
Providence Health Technologies (PHT)	FDA Small Dispenser Pilot Study
rfxcel	rfxcel Verification/Notification Readiness & Extensibility Pilot
Rymedi	DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers
Sanofi	Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder
TraceLink	DSCSA Traceability with Distributed Ledgers and Digital Recalls Project Proposal
UCLA Health	UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

Reporting Product Thefts

- FDA has verbally stated it expects reporting of product thefts on Form 3911.
- FDA views thefts as “illegitimate product.”
- But if it’s stolen, it’s not in “custody or control”?
- Further guidance expected this year.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
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.)*

Recall Draft Guidance

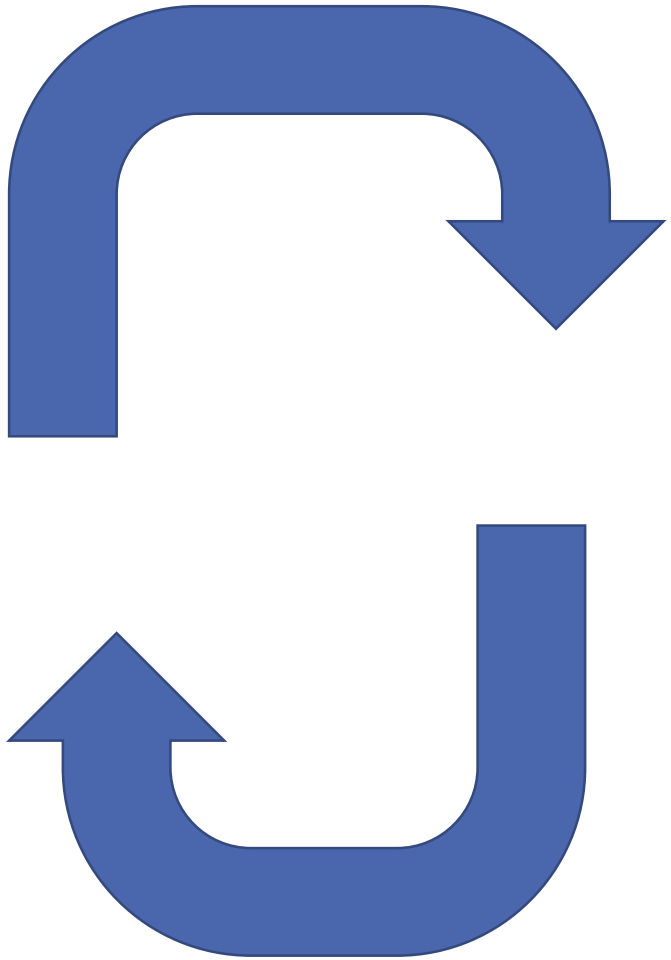
- A *Draft Guidance* implementing a *policy.*
- Applies to ***all*** FDA regulated products.
- Describes FDA expectations to maintain records to implement a recall.
- Those expectations not necessarily aligned with DSCSA timeline.

FDA Listening Session

- FDA invites supply chain stakeholders to meet with DSCSA team.
- Usually each trade association brings staff + two members.
- December 2018 was mostly governance.
- May 2019 was mostly verification of saleable returns.

Wholesale Distributor Verification Requirement for Saleable Returns

- Beginning November 27, 2019, distributors required to verify product identifier on a return prior to resale.
- FDA granted “enforcement discretion” until November 27, 2020 in September 2019 announcement.



Rationale for Enforcement Discretion

- Very large volume of saleable returns to be verified.
- Need to refine and test verification systems in actual production with real-time volumes.
- Complexities of building an interoperable, electronic system to verify large volumes efficiently.
- Immature technologies.

What Enforcement Discretion Covers

- “FDA does not intend to take action against a wholesale distributor who does not [prior to 11/27/20] verify a product identifier prior to further distributing returned product …”

- “FDA does not intend to take action against a wholesale distributor for providing a [TS] … on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements …”

What Enforcement Discretion *Does Not* Cover

- Wholesale distributor must
  - "Associate" returned product with TI and TS associated with product before resale.
  - Have verification systems to determine whether return is suspect.
  - May only buy and sell serialized product, unless product is grandfathered, or subject to waiver, exception, or exemption.
- Manufacturer must still respond to verification request if it receives one from a wholesale distributor.

- Requests and responses during testing, scale-up, and in quality and production environments.
- Negative responses.
- Data quality.
- Challenges with the Verification Router Service.
- Lack of alignment on verification responses.
- Aggressive implementation schedule continues.

Federal Drug Importation

Proposals to import “cheaper” drugs into the U.S., even though products are:

- Not labeled for U.S. market; and
- Not intended by manufacturer for U.S. market.

What's an MMA Product?

- Originally manufactured OUS.
- Authorized for marketing by another country's regulatory authority.
- Manufacturer authorizes importation for marketing in U.S.
- Subject to an FDA-approved NDA or BLA and labeling supplement.
- Differs from FDA-approved product only because labeling identifies it as an MMA product.
- Includes biologics, controlled substances, and products with REMS.

Importation of MMA products

- Manufacturer-initiated and conducted.
  - Submits labeling supplement to FDA for approval.
  - Assigns new NDC numbers.
  - Relabels product for U.S. market.
- FDA understands new NDCs might allow lower priced offerings?
- DSCSA applies once manufacturer imports product into U.S. (ATP, transaction data, serialization, etc).
- Operationally, should be like any other new item.

Proposed Rule

States, Tribes and Territories sponsor importation of certain drugs from Canada under FDA-approved Section 804 Program ("SIP").

Proposed Rule

Drugs eligible for import

Are approved in Canada and labeled by the manufacturer for the Canadian market.

Except for Canadian labeling, would meet the conditions in an FDA-approved drug application.

Excludes controlled substances, biologics, REMS drugs, infused, inhaled, intravenous drugs.

SIP Sponsor: State, Tribe or Territory

No DSCSA

DSCSA

Foreign Seller Canadian Wholesaler

Importer

SIP Sponsor: State, Tribe or Territory

No DSCSA

DSCSA

Manufacturer

Foreign Seller Canadian Wholesaler

Foreign Seller Canadian Wholesaler

Importer

Importer

Patients

Dispensers to patients

Wholesale distributors to dispensers to patients

Relabeler

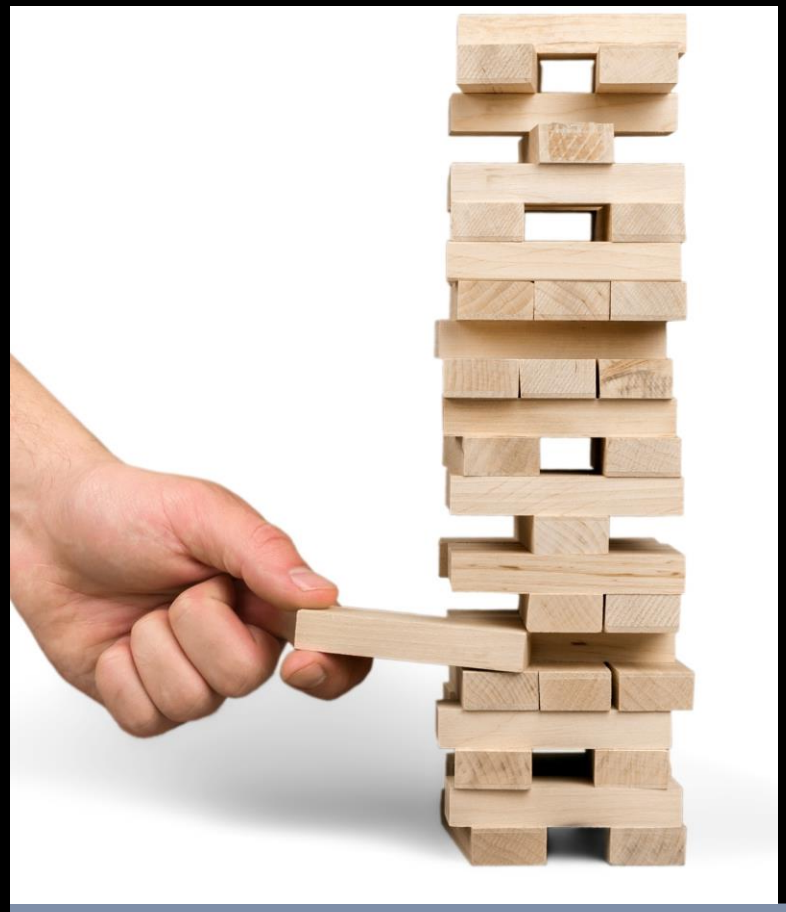
Samples to Lab for testing

Relabeler

- SIP Sponsor has to:
  - Show no additional risk to public health and safety.
  - Provide data and information on cost savings to American patients.
- SIP sponsor responsible for recalls.
- DSCSA-like requirements on Foreign Seller.

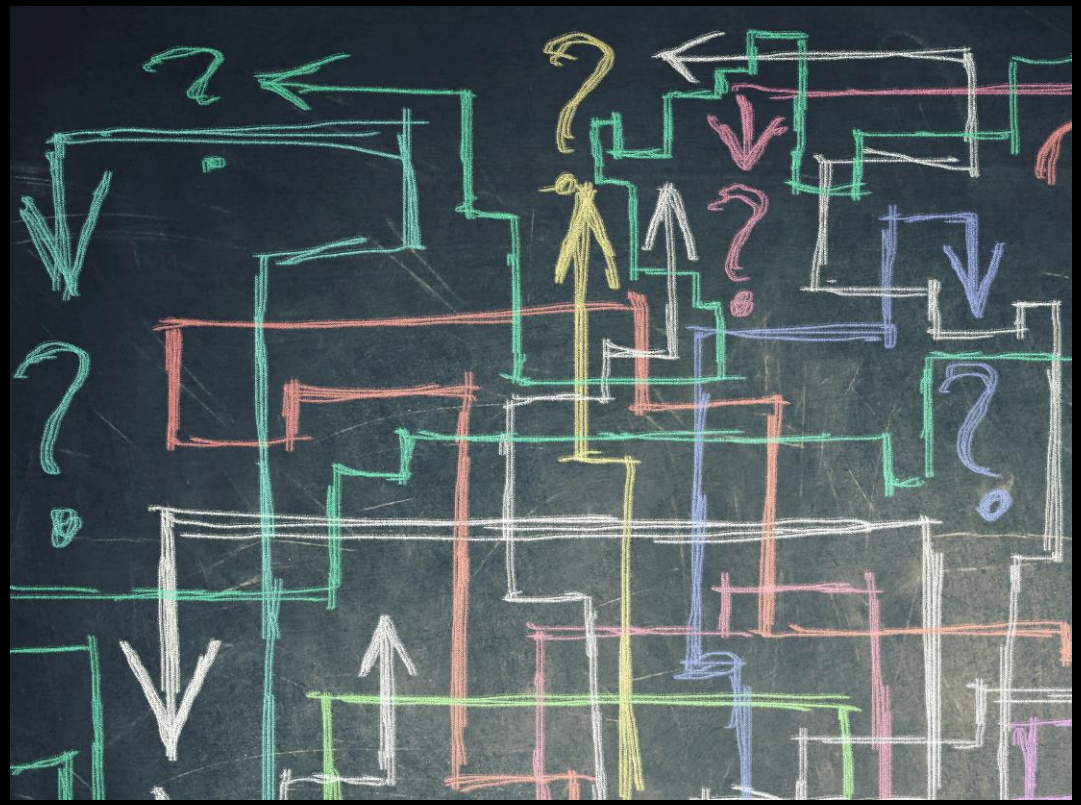
- Manufacturer-like responsibilities on U.S. Importer:
  - Statutory testing, relabeling.
  - AERs, medication errors, field alerts.
- Original manufacturer provides:
  - Information and testing protocols so statutory testing can authenticate product (unless manufacturer does testing itself).
  - U.S. labeling.

Undermining the DSCSA



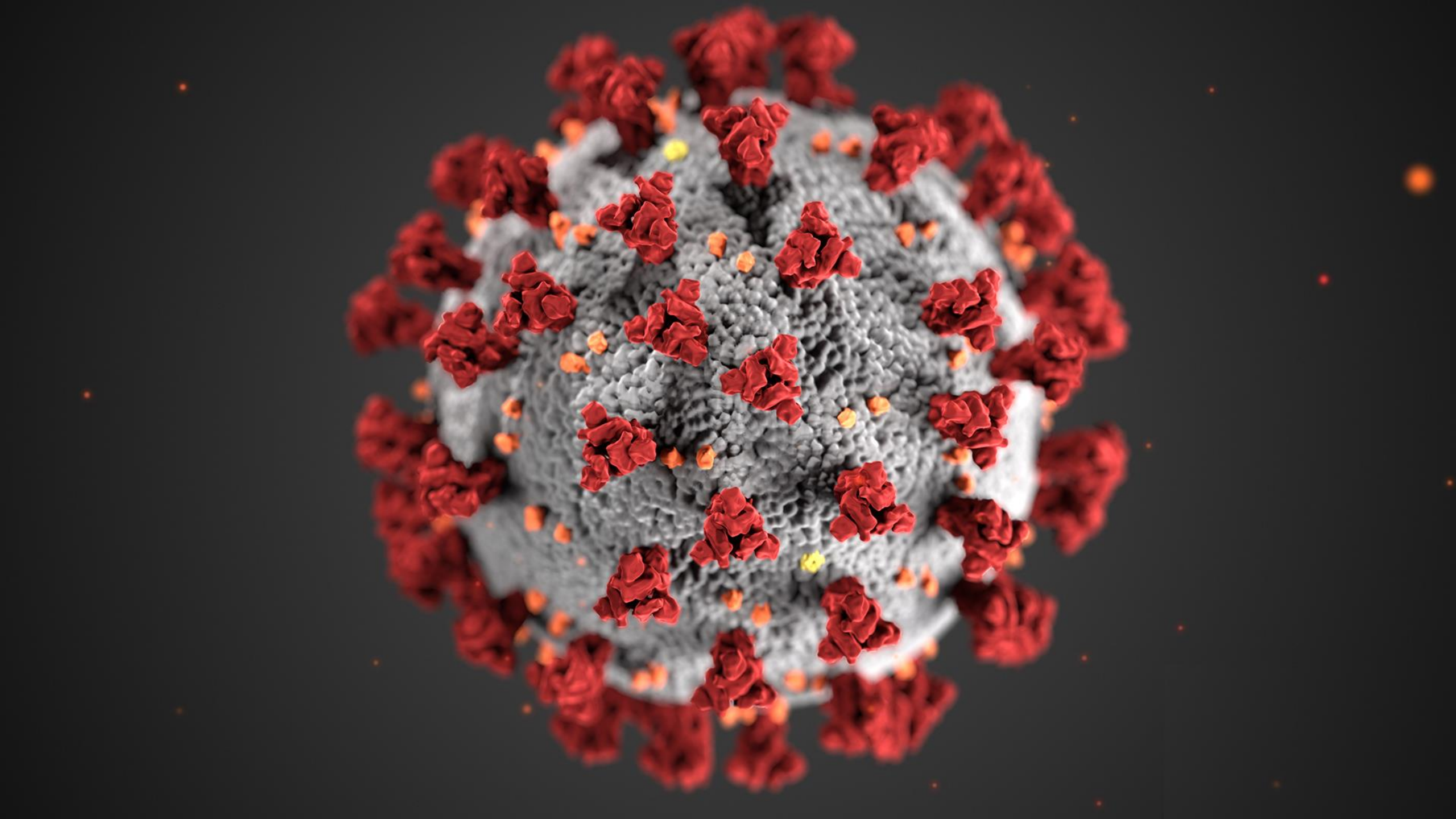
- Assumes licensure standards that don’t exist.
- Insufficient Foreign Seller requirements.
- No traceability to manufacturer.
- Can U.S. Importer comply with DSCSA?
- Complicates suspect product identification.

Other difficulties



- Adds supply chain complexity.
- Creates a patchwork (again).
- Testing complications.
- Lack of manufacturer cooperation.
- Political pressure.

What’s next?



COVID-19, FDA and DSCSA

- What has happened to you, happened to FDA, too.
- Upended workplans and agendas.
- Reassignment of staff and U.S. Public Health Service (USPHS) Commissioned Corps.
- Postponed domestic inspections unless mission-critical.

DSCSA Under COVID-19

- "[T]he distribution of a product for emergency medical reasons including a public health emergency declaration" is not a "transaction."
  - Maybe guidance on what products covered?
- Past WEEs for product from Strategic National Stockpile.
- Distributions from SNS likely not covered under DSCSA.
- But, might be other requirements.

EUA for chloroquine phosphate and hydroxychloroquine sulfate

- Issued March 28, https://www.fda.gov/media/136534/download
- Makes chloroquines available via the SNS for patients who can't participate in a clinical trial.
- EUA doesn't address DSCSA/wouldn't be a transaction, but…
- "SNS will maintain records regarding distribution under its direction of the authorized chloroquine phosphate and hydroxychloroquine sulfate(i.e., lot numbers, quantity, receiving site, receipt date)."

DSCSA Under COVID-19

- Highly likely we'll see deadline extensions, more enforcement discretion.
- A very irregular environment so document what you do.
- Normal inspections suspended, for now.
- But might have to explain later.

Enforcement and Inspection

- ~~They are coming (really)!~~
- Cannabis.
- Recalls.
- Suspect and illegitimate product SOPs.
- Data integrity.

CDER Guidance Agenda for 2020

- Definitions of Suspect Product Revised Guidance under the Drug Supply Chain Security Act.
- Identifying Trading Partners under the Drug Supply Chain Security Act; Revised Guidance.
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Revised Guidance.

November 27, 2020

- Enforcement Discretion expires for verification of saleable returns.
- New Dispenser requirements.

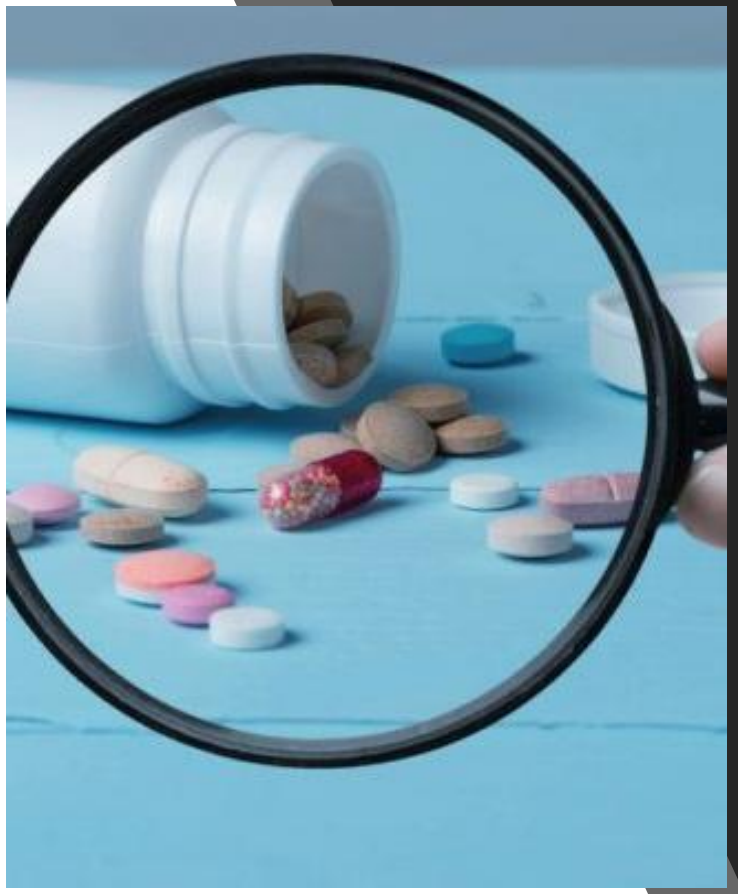
Dispenser 2020 Requirements

A dispenser may engage in transactions only with product encoded with a product identifier

Unless product is grandfathered or subject to a waiver, exception or exemption.

- Product packaged or repackaged before November 27, 2018 doesn't need an identifier.
- The absence of a product identifier can be an indicator of a suspect product.
- ***BUT***: "absent other indicia that a product may be suspect or illegitimate, the [TS] is one indication that the product was in the pharmaceutical distribution supply chain before" November 27, 2018.

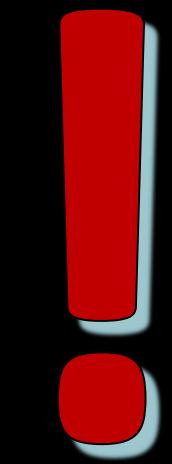
Heightened Dispenser Suspect Product Investigation Requirements



- Verify whether the lot number of a suspect product corresponds with the lot number for such product.
- Verify that the product identifier, including SNI, of at least 3 packages or 10 percent of suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product.
- Validate any applicable TH and TI in the possession of the dispenser.

Getting Ready

- Don’t panic.
- Talk to your trading partners.
- Get SOPs in place, train on them, ***and follow them***!
  - Be sure you ***can*** follow them.
- Be alert to attempts at expanding obligations beyond what the DSCSA requires now.
- Talk to your trade associations about whether you might need help.
  - Dispenser policy development isn’t on the CDER agenda.



HHS Office of Inspector General DSCSA Report (Feb. 2020)

- Released 3rd report on DSCSA implementation.
- Overall, pretty good.
  - 37 of 44 selected drug products could be traced.
- OIG was interested in getting data from trading partners the DSCSA doesn't require.
  - Recommended amending the law.
- OIG raised topics from early FDA draft guidance that HDA and others commented on.
- FDA hasn't yet responded to comments or finalized guidances.

Some final thoughts

- How long before normal returns?
- How do we get there?
- A serious reckoning over fundamental assumptions and business practices.
- Has going without normal regulation and oversight made us less safe?
    - And how would we know if it did?