DSCSA Today

Brian Waldman, Esq., MBA, Partner, Arent Fox LLP
Outline

I. Overview of Major Requirements Under DSCSA
II. FDA Guidance in 2014
III. HDMA Major Accomplishments in 2014
IV. 2015 Milestones and Activities
V. Major Challenges and Open Issues in 2015 and Beyond
I. DSCSA Major Requirements

A. Traceability (TI/TH/TS), with transition over 10 years to serialization and full electronic traceability at package level

B. Requirements for trading partners

C. Procedures to investigate and report suspect and illegitimate product

D. Federal preemption of state licensure requirements and new licensure standards for wholesale distributors and 3PLs
II. FDA “Guidance” in 2014

A. Suspect & Illegitimate Product, and Notification (draft 6/11/14)
B. Effect of Preemption Provision (draft Q&A 10/8/14)
C. Standards for Interoperable Exchange of Tracing Information (draft 11/28/14)
D. W/D and 3PL Licensure Reporting (draft 12/9/14)
E. Product Tracing (Enforcement Discretion; 12/31/14)

Not enough guidance? Too much guidance? Be careful what you wish for? Is there such a thing as “flexible certainty”?
How do we move forward?
III. HDMA Major Accomplishments

A. Formation of Traceability Implementation Working Group (TIWG)

B. Development of Transaction Scenarios and ASN Guidelines

C. Activity regarding federal preemption

D. Pressing for enforcement discretion
IV. DSCSA 2015 Milestones

Jan 1
ATP and Suspect & Illeg. Obligations

Feb 9
Licensure Draft Guidance Comments Due

May 1
Enforcement Discretion Ends

Nov 27
Waiver, Exception, Exemption, Process/Guidance; Grandfathering Specifications; WD & 3PL Licensure Std Regs

Jan 1
AATP and Suspect & Illeg. Obligations

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Nov 27
Waiver, Exception, Exemption, Process/Guidance; Grandfathering Specifications; WD & 3PL Licensure Std Regs

Jan 27
TI/TH/TS Draft Guidance Comments Due

Mar 8-11
DMC

Mar 31
Deadline for Initial WD and 3PL Licensure Reporting

July 1
Dispenser Traceability Requirements Begin

Oct - Nov
Traceability Seminar
Anticipated Additional 2015 Activities (Ongoing or Dates TBD)

- **Final FDA Suspect & Illegitimate Product and Licensure Reporting Guidances**
- **Proposed rule on state licensure standards**
- **Technical development: guidelines, serialization, pilots, aggregation**
- **Additional FDA Guidance: TI/TH/TS**
- **Public Meetings/Workshops**
- **State implementation efforts**
- **Drafts of FDA Processes/Guidances: Waivers, Exceptions, Exemptions, Grandfathering**
- **HDMA educational efforts, e.g., DMC, Traceability Seminar, Webinars**
- **PDSA participation/activities**
V. Major Challenges in 2015 and Beyond

**Bottom Line:** Many requirements of DSCSA are unclear, and some provisions may even be conflicting. If FDA interprets the requirements of DSCSA in a manner that is contrary to the interpretations that stakeholders have shared with the agency (and upon which shareholders have based their systems), compliance delays will be inevitable.
V. Major Challenges in 2015 and Beyond

DSCSA implementation is a slow moving ship (but hopefully not a sinking one)
V. Major Challenges in 2015 and Beyond (con’t)

 Fundamental Questions:

• **Who** are you *(product by product inquiry)?*
  – Manufacturer
    • NDA/ANDA holder
      – With or without contract manufacturer
    • Co-licensed partner (CLP) of application holder (or its affiliate)
      – Private Label Distributor (PLD)
    • Affiliate of application holder or CLP
      – Distributor *(exclusive distributor?)*
      – Dispenser
      – Repackager
      – 3PL
V. Major Challenges in 2015 and Beyond (con’t)

• **Who** are your trading partners?
  – Supplier
  – Customer

• **What** are you selling/trading?
  – Exemptions from the definition of “product” and “transaction”

• **What** should you pass/receive/store?
## DIRECT PURCHASE MODEL

### Transaction Information Sent

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### Transaction Statement Sent

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* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TH throughout the transmissions
SUPPLY CHAIN PRODUCT TRANSACTION SCENARIOS:
DRUG SUPPLY CHAIN SECURITY ACT IMPLEMENTATION

PRODUCT TRACING – PHASE 1

Transaction Information (TI) – includes:
+ Name of the product
+ Strength and dosage form
+ NDC
+ Container size
+ Number of containers
+ Lot number
+ Transaction date/shipment date*
+ Name and address of the seller
+ Name and address of the purchaser

Transaction History (TH) – A paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.

Transaction Statement (TS) – A paper or electronic attestation by the entity transferring ownership of the product that it:
+ Is authorized under the Act
+ Received the product from an authorized party
+ Received TI and TS from the previous seller
+ Did not knowingly ship suspect or illegitimate product
+ Has systems and processes to perform verification
+ Did not knowingly provide false transaction information and did not knowingly alter the transaction history

* Needed if shipment date is more than 24 hours after date of the transaction
V. Major Challenges in 2015 and Beyond (con’t)

• **Why** comply?
  – Failure to comply with a DSCSA requirement is a “prohibited act” under the FDCA
  – Commission of a prohibited act subjects a party to:
    • injunction of unlawful activity
    • seizure of goods
    • civil and criminal fines and penalties (**including jail**)
V. Major Challenges in 2015 and Beyond (con’t)

Tricky Issues for 2015:
• Systems compatibility (working, or head in the sand?)
  – Vendor readiness
  – Data complexities
  – Differences in statutory interpretations
  – Differences in trading partner requests
  – What to do if problem? Go/No go
V. Major Challenges in 2015 and Beyond (con’t)

Tricky Issues for 2015 (con’t):

• Authorized Trading Partner Status
  – CLP, including PLD
  – Application holder without manufacturing facility
  – Military dispenser
  – How do you confirm, and how often?
V. Major Challenges in 2015 and Beyond (con’t)

Tricky Issues for 2015 (con’t):

• Exemption of additional products?
  – PAP drugs
  – Clinical trial drugs

• TI/TH/TS
  – Abbreviated TS
  – TI dates
    • Consignment
  – Transaction scenarios
**EXCLUSIVE DISTRIBUTOR – MODEL 1**

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V. Major Challenges in 2015 and Beyond (con’t)

Tricky Issues for 2015 (con’t):

- Grandfathered product guidance
  - Product identifier
  - Tracing requirements
- Waivers (undue econ. hardship or emergency medical reasons)
- Exceptions (product identifiers)
- Exemptions (products and transactions)
V. Major Challenges in 2015 and Beyond (con’t)

Tricky Issues for 2015 (con’t):

• Odd balls:
  – 340B Program drugs
  – Sales to government for stockpile
  – Drop shipments

• FDA licensure standards for wholesale distributors and 3PLs
  – Timeline
  – State options
V. Major Challenges in 2015 and Beyond (con’t)

Tricky Issues for 2015 AND BEYOND (con’t):

• Serialization and Related Issues
  – Pilot projects (serialization, inference, aggregation)
  – FDA public meetings and guidance document on unit level tracing and interoperable data exchange
  – Serialization efforts
  – Verification
    • Manufacturer: 4 years (respond to requests; investigation and return implications)
    • Repackager: 5 years (respond to requests; investigation and return implications)
    • Distributor: 6 years (investigation and return implications)
    • Dispenser: 7 years (investigation implications)
  – End game: Interoperable electronic systems for unit level product tracing