Sponsored article

New Bookend to Drug Supply Chain Management in the U.S.

By Kathleen M. Sanzo

In 2012, as a result of the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA), FDA began a concerted effort to ensure the quality and integrity of the supply chain for pharmaceuticals. Title VII of FDASIA gave FDA new authorities to address the risks inherent in a global supply chain. Since passage, FDA has moved quickly to issue regulations on product detentions,[1] higher penalties,[2] and guidelines concerning quality agreements,[3] among other issues.

FDA's efforts to control and manage the drug supply chain are now further enhanced by new requirements related to the distribution of pharmaceutical products – the other bookend to supply chain management.

In November 2013, the President signed the Drug Supply Chain Security Act (DSCSA), P.L. 113-54, into law. The new law creates a federal track and trace system and is intended to further solidify FDA's efforts to secure and validate the supply chain for drugs. It is also intended to head off the efforts of several states such as California and Florida to enact far-reaching and conflicting state pedigree laws for drugs. DSCSA is intended to result ultimately in a lot level tracing system developed over the next ten years.

The DSCSA's additional new demands relating to the distribution of drug products will also have contractual and other commercial implications that companies should consider as they develop implementation strategies. Current estimates are that medium-sized drug manufacturers will spend $36M to implement a serialization and traceability system and approximately $7M/year to maintain and comply with the new systems.[4] The scope of these investments means that significant thought and advance planning to effective implementation is necessary.

Requirements of DSCSA

Under DSCSA, manufacturers, wholesalers and retailers of prescription drugs have new documentation and procedural requirements. In brief summary, the principal requirements are:

Manufacturers are required by:[5]

- January 1, 2015, to deal only with authorized trading partners.
- January 1, 2015, to provide subsequent owners with transaction history, information and statements in a single (paper or electronic) document.
- January 1, 2015, to maintain all required transaction information, history, and statement for 6 years.
- January 1, 2015, to provide FDA or state officials, for a recall or for investigating suspect or illegitimate products, transaction information, statements and histories within two business days.
- January 1, 2015, to have SOPs (Standard Operating Procedures) for product at the package level for identifying suspect products, quarantining product, investigating suspect and illegitimate products, notifying FDA and immediate trading partners of illegitimate product, and otherwise clearing the product.
- 2017, to provide all transaction information in electronic format to trading partners.
- 2017, to affix or imprint a product identifier on each package or homogenous case of drug product.
- 2017, to have systems for verifying product at the package level for trading partners within 24 hours of the request.
- 2017, to have systems for verifying product considered resaleable.

Wholesalers are required by:[6]

- January 2015, sell only to authorized trading partners.
- January 2015, to be licensed in all states from which the wholesaler distributes drugs or, in the absence of state laws, from FDA, once federal standards are published.
- January 2015, to provide to FDA annual reports of the wholesaler's licensed status in all states, and, within a reasonable period of time, any disciplinary actions against the firm.
- January 2015, to provide transaction information, history and statements that the wholesaler is an authorized distributor, i.e., licensed and did not knowingly provide false information or ship an illegitimate product, to downstream customers.
- Maintain the transaction information, history and statement for 6 years.
- January 2015, to begin to have systems/SOPs to identify suspect and illegitimate product, quarantine product, conduct suspect product investigations, and provide notices to FDA and immediate trading partners if the wholesaler has determined the product to be illegitimate, and otherwise to clear product, with FDA approval.
- 2019, to accept only serialized drug products.
- 2019, to verify serial numbers of all saleable returns, and be able to associate returned product with its original transaction history.

Dispensers (Retail Pharmacy) are required by:[7]

- January, 2015, to use only authorized trading partners and respond to requests for information about shipments.
- July, 2015, to not accept ownership of a product unless the previous owner at the time of, or before the transaction, provides transaction information, history and statements.

- January, 2015, to have systems for illegitimate and suspect product investigations and quarantine notices to FDA and trading partners, and record-keeping for 6 years.
- July, 2015, if transferring ownership to a non-patient, to provide transaction history to the subsequent owners.
- July, 2015, to capture transaction information adequate to investigate suspect product
- 2020, to sell only product with product identifiers.

Note: Dispensers can use third parties including authorized wholesale distributors to maintain all required transaction information and histories, and can return product to a trading partner without providing transaction information.

Which Products are not subject to DSCSA?[8]
- eligible medical convenience kits
- medical gases
- homeopathic drugs
- blood or blood components
- compounded drugs
- IV fluids and dialysis drugs, sterile water
- OTC drugs and grandfathered drugs
- device combination products

Which transactions are not subject to the DSCSA?[9]
- direct-ship orders where ownership does not change
- intra-company transfers
- transfers during public health emergencies
- transfers of exempt products
- transfers to and from charitable organizations
- shipments of drug samples

What is in Transaction Information?[10]
- drug name, strength, dosage
- container size, number of containers in a box
- lot number (includes serial number starting in 2023)
- transaction date and ship date
- business names and addresses of trading partners

What is a Transaction History?[11]
- All transaction information back to the manufacturer of the product

What is a Transaction Statement?[12]
- Statement that the entity providing it is authorized / licensed, received product from an authorized party and received transaction information and statement from a prior owner, and did not knowingly provide false information or ship an illegitimate product

What is Suspect Product?[13]
- Product for which there is a reason to believe it is:
  - potentially counterfeit, diverted or stolen
  - potentially intentionally adulterated such that the product would result in a serious adverse health consequences or death
  - is potentially the result of a fraudulent transaction
  - it appears otherwise unfit for distribution such that its use would result in serious adverse health consequences or death

What is an Illegitimate Product?[14]
- Product for which "credible" evidence shows that it is:
  - potentially counterfeit, diverted or stolen
  - potentially unintentionally adulterated such that the product would result in a serious adverse health consequences or death
  - potentially the result of a fraudulent transaction
  - otherwise unfit for distribution such that product use would be reasonably likely to result in an serious adverse health consequences or death

What are the red flags/signs for suspect product, according to FDA?[15]
- Unsolicited offers to purchase product from unfamiliar/unknown sources
- Delayed or deferred provision of transaction history, information, or statements
- Products in short supply or extremely expensive
- Unusual appearance of labels including physical damage, missing information, smudged print, bubbling labels; unexpected foreign sources of the product

What happens if a suspect product emerges in the distribution chain?
- Product must be quarantined until a suspect product investigation is completed and the product is found to be either cleared or illegitimate.
- Once cleared, the distributor should send a notice to FDA and then can begin distributing
- If the product is determined to be illegitimate, then FDA and all immediate trading. partners must be notified; distribution of the product cannot restart until a notice has been filed with FDA and FDA agrees with re-distribution.

Potential Legal Implications on Commercial Activities from DSCSA

As with all substantial new regulatory or compliance requirements, they tend to affect in unpredictable ways the commercial functions of affected companies. Although DSCSA will require substantial changes in IT and other technology systems critical to identifying each unit of a drug and tracking it throughout the distribution chain in the U.S., there are many other potential commercial functions and practices likely to be affected by DSCSA. These include:
- Contractual Provisions with Trading Partners—commercial terms likely to be affected include:
  - Delivery process / returns process
  - FDA guaranties
  - Compliance with laws / provisions
  - Recordkeeping requirements
  - Audit rights and responsibilities
  - Obligations of cooperation with trading partners on suspect and illegitimate product investigations
  - Data sharing (customers lists?) and confidentiality
  - Insurance requirements for recalls, market withdrawals, quarantines
  - Cost allocation / liquidated damages for DSCSA non-compliance
- DSCSA will require a substantial number of new/modified SOPs, training, and auditing of compliance on:
  - Development of transaction information, history and certifications
  - Verification of state licenses and trading partners
  - Investigations of suspect and illegitimate product
  - DSCSA quarantine processes and sample retention
  - Disposal of affected products/processing of returns
  - Recordkeeping
- DSCSA may create conflicts with existing customer protocols on sales returns, etc., which must be negotiated and resolved.

- DSCSA will require a new internal function to determine if a product is "suspect," or what level of evidence is "credible;" legal assistance in making these determinations will be useful.
- DSCSA creates potential new legal liabilities for false certifications or knowingly providing illegitimate product; DSCSA certifications may provide new bases for False Claims Act challenges for companies.
- DSCSA will likely result in more commercial disputes concerning which party is responsible for suspect or illegitimate product, or how to handle such product.
- With regard to quarantined product which is eventually found not to be illegitimate, there may be disputes over which party will pay for holding the product while FDA is reviewing the termination notice; as there is no timeline on FDA's approval of the release notice, held inventory can aggregate, causing market disruption, warehousing fees, broken contracts, and drug shortage/patient access issues.

Finally, although preemption of similar state pedigree laws was a driving force behind DSCSA, the extent of actual preemption on wholesale licensing is still a question in some states which do require licensing for products exempt from DSCSA and where state laws may be stricter that required by DSCSA. Therefore, companies should carefully review their state laws to ensure they continue to be in compliance during this transition period.

These and other potential implications will need to be considered as companies begin to understand the legal and commercial implications of this new law.

---

1 79 Fed. Reg. 30716, May 29, 2014.
2 Amendments to U.S. Sentencing Guidelines, April 30, 2013, at Section § 2B5.3(b)(5) relating to offenses involving counterfeit drugs.
3 Food and Drug Administration, Guidance for Industry, Contract Manufacturing Arrangements for Drugs: Quality Agreements, May 2013, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm353925.pdf
4 See "Manufacturers Estimate Price Tag for Track and Trace," Drug GMP Reports, May 2014.
5 Federal Food, Drug, and Cosmetic Act (FFDCA) § 582(b) et seq.
6 See FFDCA § 582(c) et seq.
7 See FFDCA § 582(d) et seq.
8 See FFDCA § 581(24).
9 See FFDCA § 581(24)
10 See FFDCA § 581(26).
11 See FFDCA § 581(25).
12 See FFDCA § 581(27).
13 See FFDCA § 581(21).
14 See FFDCA § 581(8).
15 Food and Drug Administration, Guidance for Industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, June 2014, available at http://www.fda.gov/ downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf