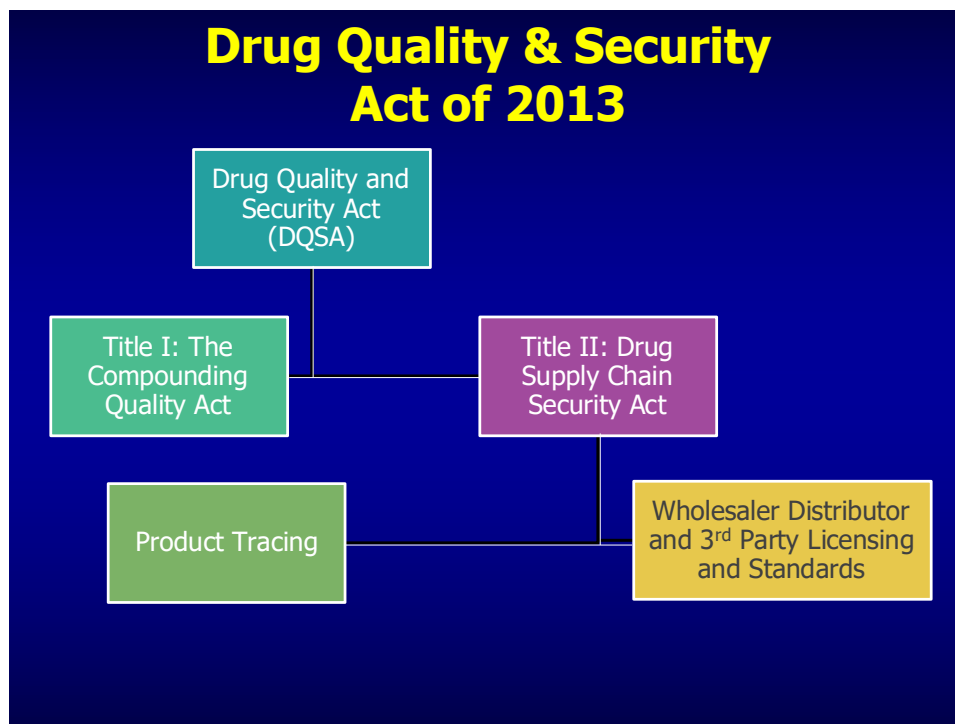


Catalyst Corner: Provisions Delayed with Drug Supply Chain Security Act While Counterfeits Continue

Having just wrapped the 2024 ASAP Annual Conference, readers who attended got the latest update on the Drug Supply Chain Security Act (DSCSA) from speaker Randy Hoggle. You may recall the DSCSA called for the creation of a uniform, national standard for tracing pharmaceuticals through the supply chain. Specifically, it outlined a timeline for implementing a new electronic, interoperable system for product tracking and tracing over a 10-year period ending November 27, 2023. According to the FDA, the new system would allow them to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

DSCSA was part of The Drug Quality and Security Act (DQSA) that was signed into law on November 17, 2013. The DQSA's purpose was to address issues related to drug compounding oversight, and incorporates a national prescription drug "track and trace" system inclusive of standards for prescription drug wholesale distributors and third-party logistics providers (3PLs). DQSA amended the Food, Drug & Cosmetic Act (FDCA). Title 1 of the DQSA addresses the compounding provisions through the Compounding Quality Act (CQA). The impetus behind the CQA was contaminated compounded drugs that led to the death of more than 60 people and infected more than 750 patients in the fall of 2012. Title 2 of the DQSA is the DSCSA.



The key provisions that were to be implemented by 2023 are requirements for:

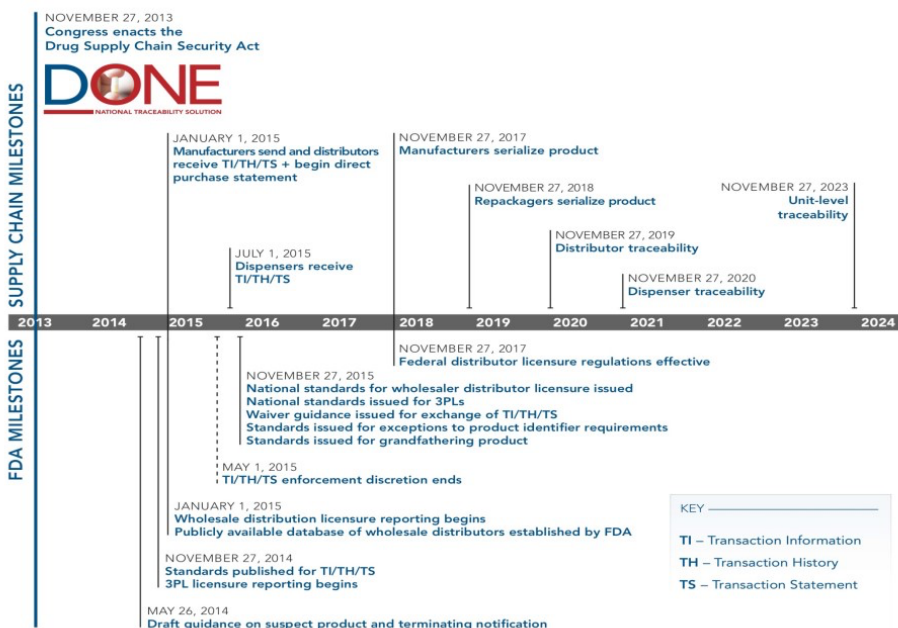
- **Product identification:** Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.

- **Product tracing:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- **Detection and response:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- **Notification:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.
- **Wholesaler licensing:** Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

All prescription drugs in finished dosage forms for human use are subject to the DSCSA traceability rules which begin with the manufacturer and include the direct purchase repackager and exclusive distributor as the start of the supply chain. The chain of product ownership, rather than possession, is what is tracked through the entire supply chain and transaction detail must be presented at the point of product receipt. In addition, the FDA website offers a number of resources, including those found here: <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

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FEDERAL IMPLEMENTATION TIMELINE



There were several milestones along the DSCSA’s implementation timeline, detailed in the figure below.

- 2014-2015 saw 3PL and wholesale distributor reporting to the FDA and national licensure standards for these groups.
- 2015 required trading between authorized partners and product tracing and verification and the ability to investigate suspect product
- 2017-2018 saw manufacturers implementing the serialized product identifier on an individual packages
- 2019 called for distributor traceability using product identifiers , including for saleable product returns
- 2020 called for dispenser traceability using product identifiers
- 2023 called for a complete, interoperable system.

Nearly every deadline outlined in DSCSA has had enforcement delayed because of the industry's lack of readiness vis-à-vis an interoperable system. Numerous industry pilots have been undertaken, some related to the overall interoperable system, others related to a system to verify salable returns—called the verifiable return system or VRS. During the ten year timeframe, standards have been created for the unique product identifier using the GTIN: global trade information number. In addition, data transmission standards have been crafted using the EPCIS (electronic product code information standard) from Global Standards Organization. EPCIS will eventually replace X12 ASN's in an interoperable system.

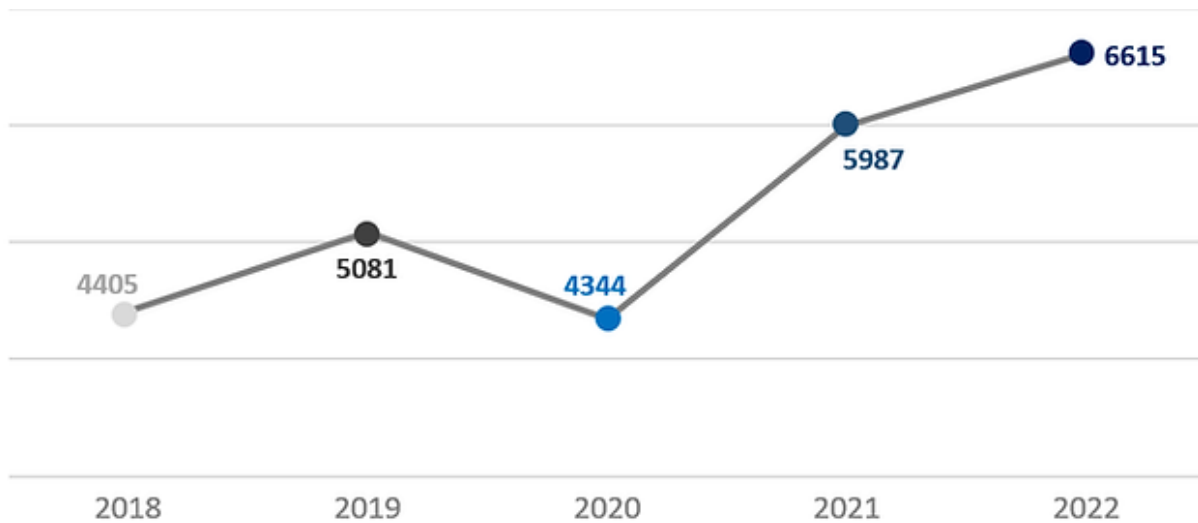
Randy's presentation outlined status of the current DSCSA federal regulatory compliance enforced requirements, remaining and additional requirements. He also briefed attendees on supply chain capabilities and remaining issues. He also addressed the regulatory, staffing, and financial impact on the ATP community to date and over the next three to five years. A good review of industry readiness is the Healthcare Distribution Alliance's 2022 Serialization Readiness Survey, available for download at: <https://www.hda.org/publications/2022-serialization-readiness-survey/>

The bottom line: there is still much to be done to get to the DSCSA's vision of an electronic, interoperable system to trace pharmaceutical products in the US and reach FDA's vision of using this system to address counterfeit products even though all supply chain participants have had to have a way to investigate suspect products since 2015.

Counterfeit products remain a problem and the types vary based on market conditions and demand. During the COVID-19 pandemic, there were a number of counterfeit KN-95 masks circulating, especially given the shutdown of numerous medical product and pharmaceutical production facilities as the pandemic hit different countries. Popular lifestyle drugs have always found a place in the counterfeit product supply as have high-priced, high-demand products. Trends in counterfeit, illegal diversion and theft incidents have been tracked by the Pharmaceutical Security Institute, PSI, www.psi-inc.org.

PSI was founded in Washington C.C. in 2002 by the Security Directors from fourteen major pharmaceutical companies. Working with its members, the PSI developed improved systems to identify the extent of the problem and to assist in coordinating international inquiries. Today, PSI membership includes over forty pharmaceutical manufacturers from many nations. The PSI has established representational offices with staff in Singapore and Stockholm, Sweden.

In 2022, incidents increased by over 10% to 6,615.



Source: PSI

An analysis of those 6,615 incidents found:

- Pharmaceuticals in every therapeutic category were targeted by criminals
- 2,370 different medicines were involved in these incidents
- This represented a twenty-five percent decrease (-25%) from CY 2021
- As many as 280 different medicines were discovered in a single incident

The categories most frequently targeted by individuals engaged in pharmaceutical counterfeiting were genito-urinary, central nervous system (CNS), and anti-infective. The latest counterfeit products are being found among today's popular, short-supply glucagon-like-peptide-1 (GLP-1) agonists. GLP-1 agonists have been used to treat diabetes and now, for weight loss. Popular drugs include dulaglutide (Trulicity), exenatide (Bydureon), liraglutide (Saxenda, Victoza), semaglutide (Ozempic, Rybelsus, Wegovy), tirzepatide (Mounjaro, Zepbound). In late December, the FDA said it has seized 'thousands of units' of counterfeit Ozempic that had been ***distributed through legitimate drug supply sources***. According to a statement, the agency "and the drug's maker, Novo Nordisk, are testing the shots," but "do not yet have information about the drugs' identity, quality or safety," according to reporting by the Associated Press (<https://apnews.com/article/ozempic-fake-counterfeit-semaglutide-86d152c78f180792e7764a435cb3334d>).

Given the countless calls my colleagues and I have been fielding for the last year from patients with prescriptions for these drugs, all of which are in short supply at various times, I expect counterfeiting and profiteering to continue.

Ten years after the passage of the DSCSA and its vision for an electronic, interoperable system for tracking and tracing prescription drug products by November 27, 2023, it's unfortunate such a system remains unattained at a time when it continues to be needed. Stay tuned.