



## Help! I Need Somebody: FDA to Hold a Public Workshop Concerning the Drug Supply Chain Security Act

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Congress, the Food and Drug Administration, the pharmaceutical industry, and the general public are concerned about ensuring the safety and security of the pharmaceutical distribution supply chain. The Drug Supply Chain Security Act (DSCSA), to be discussed, attempts to tackle such concerns. On April 5 and 6, 2016, channeling John Lennon and The Beatles, the Food and Drug Administration will seek help from everybody, by holding a public workshop at the agency's White Oak Campus in Silver Spring, Maryland, and soliciting comments to review pilot projects.

This Bulletin will provide a high-level overview of the DSCSA (not the FDA's guidances issued to date), and highlight the public workshop's objectives.

### High-Level Overview

- The DSCSA, part of the Drug Quality and Security Act, became law on November 27, 2013
- The DSCSA outlines a 10-year plan to establish a standard electronic, interoperable track and trace system for prescription drugs
  - a national, uniform system for tracking prescription drugs, as opposed to the varying requirements that have been implemented over the years by some states
- Companies can expect greater regulatory oversight and additional documentation requirements as FDA issues implementing regulations and guidance
- Key provisions to be implemented include requirements for product identification, tracing and verification; suspect drug detection and response;<sup>1</sup> notification of illegitimate drugs; wholesaler licensing, and third-party logistics provider listing
- As of January 1, 2015, the law requires that trading partners implement systems to quarantine suspect product in their possession or control and conduct an investigation to determine whether the product is illegitimate<sup>2</sup>
- Beginning July 1, 2015, most pharmacies in the U.S. are required to have systems in place to receive transaction information regarding the prescription drugs they purchase from suppliers
  - the so-called "3T" information (Transaction History, Transaction Statement, and Transaction Information) for each prescription drug it purchases on or after July 1
- The DSCSA creates specific obligations for each type of trading partner (*i.e.*, manufacturers, repackagers, wholesale distributors, and dispensers of prescription drugs, such as pharmacies), and third-party logistics providers who provide logistics services for the drug product but do not take ownership or have responsibility to direct the sale of the product

<sup>1</sup> A "suspected product" is defined in the statute as a product for which there is reason to believe it: (1) is potentially counterfeit, diverted, or stolen; (2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) is potentially the subject of a fraudulent transaction; or (4) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

<sup>2</sup> An "illegitimate product" is defined as a product for which credible evidence shows that the product: (1) is counterfeit, diverted, or stolen; (2) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) is the subject of a fraudulent transaction; or (4) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

## Track and Trace

- The DSCSA implemented what is known as a pharmaceutical “track and trace” system, so named because it requires manufacturers to label products with tracking numbers (allowing them to be tracked), and allowing any suspect product to be traced back to its point of origin into the system by mandating strict record-keeping requirements
- That number and other information must be recorded each time a drug passes through the pharmaceutical supply chain, such as from a drug manufacturer to a wholesaler or a wholesaler to a retailer
- If a counterfeit medicine is introduced into the supply chain, it will therefore be easier to determine its point of entry by examining the records of each entity
- FDA is required to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain
- The goals of this program include: (1) assessing the ability of supply chain members to comply with the law and to identify, manage, and prevent the distribution of suspect and illegitimate drugs; (2) identifying the system attributes needed to implement the legal requirements, such as the requirement to utilize a product identifier for product tracing purposes; and (3) demonstrating the electronic, interoperable exchange or product tracing information across the pharmaceutical distribution supply chain

## Public Workshop

- FDA intends that the public workshop will provide an opportunity for interested persons to provide comments on, and discuss the objectives of, pilot projects designed to implement the legal requirements and to enhance the safety and security of the pharmaceutical distribution supply chain
- FDA seeks input on the issues identified above
- FDA also wants to learn more about the practices, processes, and systems that supply chain stakeholders currently use, or plan to use, to meet the new legal requirements, particularly the product tracing and verification requirements

If any interested company would like assistance in submitting comments or presenting in person, please let AGG know. Alan Minsk will also be presenting at the International GMP Conference on March 9, 2016, about “Legal and Policy Issues for Regulating the Drug Supply Chain.”<sup>3</sup> If you would like to hear more about the conference or receive a copy of the handout, let us know.

<sup>3</sup> <http://internationalgmp.com/agenda/>

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