The Drug Supply Chain Security Act Implementation: FDA's Public Workshop on Proposed Pilot Project(s) Under the Drug Supply Chain Security Act

THIS IS A SUMMARY OF SOME OF THE COMMENTS SHARED BY PUBLIC WORKSHOP PARTICIPANTS. IT IS NOT COMPREHENSIVE BUT REFLECTS THE RECURRING THEMES HEARD. THIS SUMMARY SHOULD NOT BE INTERPRETED AS A FINAL DECISION OR POSITION OF THE FDA.

Under section 582(j), 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. On April 5-6, 2016, FDA held a public workshop on "Proposed Pilot Project(s) Under the Drug Supply Chain Security Act." The workshop provided a forum for stakeholders in the drug supply chain to facilitate the productive exchange of information and ideas. The information gathered from the workshop and the public comments submitted to the docket will further inform FDA's development of pilot project(s) under the Drug Supply Chain Security Act (DSCSA). Over 100 participants attended the workshop, representing a broad spectrum of stakeholders including drug manufacturers, repackagers, contract manufacturing organizations, wholesale distributors, third-party logistics providers, dispensers (pharmacies), a standards organization, solution providers, and consultants.

Goals of the Public Workshop

- To obtain stakeholder input on proposed objectives of pilot projects
- To obtain stakeholder input on evaluation methods of the pilot project objectives identified from group discussions

Workshop Structure and Process

The workshop was structured around two discussion sessions, each introduced with a short FDA presentation. Workshop participants were organized into small groups for initial discussions that were facilitated by an FDA moderator. The small groups were assigned so that a mixture of supply chain stakeholders would be represented. The small groups came together for the large group discussion. The first session focused on the proposed pilot project objectives. Participants were asked to consider what may be an important objective to be piloted, how might the objective be accomplished in a pilot, what are the challenges, and how do you overcome the challenge(s). FDA provided the following categories of overarching objectives that proposed pilot project objectives may fall into:

Overarching objectives

- Integration of the DSCSA's product-tracing requirements into daily operations (e.g., product sales, purchasing, and distribution)
- Verification of suspect or illegitimate product (including the determination and handling)
- The ability of pharmaceutical distribution supply chain members to exchange product tracing information accurately, efficiently, and consistently among trading partners (e.g., interoperability)

The second session focused on evaluation methods of the pilot project objectives identified. Participant were asked to consider how do we know if a pilot project has accomplished its objective, how can this objective be measured (qualitatively or quantitatively), what do we expect to learn from this evaluation, and how should the results of a pilot project be used. FDA suggested that evaluation methods may provide information related the following:

Evaluation factors

- Baseline measures: To understand current practices and operations from the point of view of the pre-pilot process being examined.
- Projections and insights: To understand how the experience and observations might apply to other trading partner types or sizes or product types, in addition to the pilot project outcomes and differing results of similar pilot projects.
- Scalability implications: To understand how controlled, small-scale versions of projected operations would change when increased in both the number of product or operations or in trading partner types and sizes.

Group discussions identified common themes, considered differing trading partner size and capabilities, and identified challenges of pilot project objectives. Participants provided ideas about evaluation methods of the pilot project objectives identified from group discussions.

Highlights of the Workshop Discussions

The following table summarizes what was heard from workshop participants as objectives and evaluation methods to consider in the development of pilot projects. (Column 1 lists the discussion category, column 2 lists the pilot project objectives identified during group discussions, and column 3 lists the evaluation methods identified during group discussions. It is important to note that there is no direct or implied one-to-one relationship between the bullets in columns 2 and 3.)

Column 1	Column 2	Column 3
Discussion Category	**Pilot Project Objectives**	**Evaluation Methods**
General Considerations	• Ensure adequate mix of products and packaging levels represented • Include all stakeholders (types and sizes) and different transactions • Flexibility of pilot projects (different partners, evolving scenarios, additional use cases and special scenarios) • Risk-based approach to determine what to pilot (e.g., target known weaknesses in the supply chain) • Timing of pilots, to make them useful as trading partners implement requirements • Human factors that could lead to challenges (errors, challenging business practices)	• Metrics should focus on end-to-end supply chain and also specific operations • Use initial pilots to identify other pilots based of severity or frequency of issue(s) encountered • Measure and report results of risk-based tests for specific use case / product tests • Simulate illegitimate products/transactions to test a process or system • Document costs to implement, use, and maintain piloted solutions • Document experience level and role of pilot partners doing the piloted activities – enables comparison of results from high and low experience partners

Column 1	Column 2	Column 3
Discussion Category	**Pilot Project Objectives**	**Evaluation Methods**
Product Identifier	• Method used to issue and manage serial numbers (including CMO's role if applicable) • Compare different representations for the product identifier (10 or 11 digit NDC used in the SNI,. 14-digit GTIN)	• Measure impacts of different representations of the SNI (GTIN vs. SNI) on systems or processes - Number of errors - Time to process - Time to reconcile these differences
Bar Code Quality	• Readability of bar code printed or affixed (environmental and human factors) • Convergence of linear and 2D barcodes on product – distinguishing which barcode to read/use and when	• Measure barcode read error rates - Number of items unnecessarily quarantined or held-up - Measure time and resource impacts
Interoperability	• Process and technical challenges due to variety of solutions expected - Central database vs. decentralized (peer-to-peer) - Trading partners with systems vs. others with little to no systems or using someone else's system • Maintaining visibility of the serialized product throughout the distribution supply chain - What to do when: a trading partner goes out of business or one acquires another business - Evaluate the use of Electronic Data Interchange(EDI), Electronic Product Code Information Services (EPCIS), and other solutions separately	• For both decentralized and centralized models, time implications - To investigate suspect and illegitimate products - For notifications required within the statutory timelines - For scalability – in regards to the time and ease of use when scaled up from pilot to full production • Product tracing information (across multiple partners) - Capability to retrieve the information - Time for retrieval and transfers of information - Accuracy of the information (within and between systems) • Security and access - Evaluate and document access levels for trading partners

Column 1	Column 2	Column 3
Discussion Category	**Pilot Project Objectives**	**Evaluation Methods**
Data / Database/System Issues	• Performance measures (e.g., how to evaluate data from beginning to end of the product lifecycle and vice versa, how system performs when full or partially loaded with data) • Evaluate data format or processes for data transfer - Use of technical standards for defining data attributes to enable interoperable transfers - Methods to handle the "master data" (product-specific data) and transaction data separately to minimize "master data" redundancy • Integration into individual/company data systems • Controlled/limited access to data by trading partners, FDA or other federal or state officials (data governance) • Product status at all packaging levels (each, case, pallet): e.g., ability to report status such as whether expired, illegitimate, in error, quarantined	• System Performance and Effectiveness - Time to access and use product tracing information, once that data is received into a system - Quality of product tracing information • Operational impacts - Data and product flow ▪ Number of system interactions within one, and amongst multiple, trading partners ▪ Time and resource changes on operations when data and product not moving at same time (e.g., product arrives before data arrives) - Time for location/ownership/status changes to be reflected in the system - Time of product flow delays and associated costs due to system or data problems
Aggregation / Disaggregation	• Test multiple levels of adoption of inference, by different trading partners • Impacts when inference is used vs. when inference is not used; impact on trading partners • Identify gaps in data or errors, accuracy of data, particularly downstream when searching or examining the data; how can errors be corrected • When in distribution that inference no longer needed (e.g., the case is opened and individual packages are unpacked) • Impact on aggregation by product sampling (e.g., U.S. Customs may open and take samples)	• Number of system and product interactions within one, and amongst multiple, trading partners • Time required to conduct aggregate/disaggregate operations and transactions • Accuracy of aggregation data (measure error counts) • Time to gather aggregation/disaggregation data for investigations and notifications
Verification / Notification	• Communication to brand owner when a suspect product is found or when illegitimate product is found and reported to FDA • Process for investigation of suspect or illegitimate product (including all applicable trading partners), including testing boundaries of the system • Number of connections /queries needed to gather product traceability information in response to a verification or notification request • Using 2D barcode at the dispenser level (for verification or other purposes, determine training of personnel or equipment needed)	• Response times: current vs. future process • Time needed to obtain product tracing information to respond to a request for verification • Time to gather product tracing information to support an investigation for a suspect or illegitimate product, or a recall • Percentage of items that are successfully verified vs. those that were targeted for verification

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Discussion Category	**Pilot Project Objectives**	**Evaluation Methods**
Exception Handling / Errors / Inconsistencies	• Focus on 'honest mistakes and errors' (includes aggregation error) • What triggers a suspect product or makes it non-saleable, vs. the 'honest errors' • Fixing over/under shipments (when more data is needed or more product is needed)	• Measure percent errors detected: compare exceptions introduced vs. exceptions detected - Identify the first step in the process where error detected • Number of new or changed processes needed to accomplish DSCSA goals - Measure time and resource impacts • 'Honest Errors' - Number of items unnecessarily quarantined or held-up - Measure time required to detect and correct errors • Measure barcode read error rates - Number of items unnecessarily quarantined or held-up - Measure time and resource impacts
Special Scenarios	• Situations where data and product do not necessarily move together, which changes data governance and where data goes (e.g., drop shipments, 340B products, investigational drugs) • Repackaging: How to effectively and reliably link newly-issued product identifier back to original manufacturer product identifier • Situations with 'mixed product' (e.g., when transactions involved product along with product that is subject to grandfathering, a waiver, exception, or exemption, or serialized product along with non-serialized product)	• Measure error rates for special processes - Number of items unnecessarily quarantined or held-up - Measure time and resource impacts • Measure accuracy of linkage between original manufacturer product identifier and repackager-issued product identifier

Next steps

FDA intends to establish a pilot project program to implement section 582(j) of the FD&C Act. The overarching goals of this program will reflect the project design goals identified in section 582(j)(B), and may include, in particular, assessing the ability of supply chain members to satisfy the requirements of section 582 and to identify, manage, and prevent the distribution of suspect and illegitimate drugs; identifying the system attributes needed to implement the requirements of section 582, particularly the requirement to utilize a product identifier for product tracing purposes; and demonstrating the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain. FDA intends to continue coordination of its pilot project program efforts with stakeholders across the pharmaceutical distribution supply chain.