



U.S. Food and Drug Administration

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Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; FDA Public Workshop Summary

THIS IS A SUMMARY OF MAIN 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.

OVERVIEW OF THE PUBLIC WORKSHOP

The Track and Trace Public Workshop took place on February 15-16, 2011. Approximately 120 participants attended, representing a broad mix of stakeholders and perspectives. The Public Workshop took a dynamic and innovative approach to gathering public input in two aspects: content-sharing and discussion sessions.

The workshop began with an overview of system goals, potential attributes, and a review of track and trace concepts and terminology by FDA staff. Virginia Herold, Executive Director of the California State Board of Pharmacy, described California's e-Pedigree requirements. Discussion sessions followed the presentations and were carried out as round-table discussions of 7-9 participants, guided by a moderator. Each table consisted of a variety of supply chain stakeholders (i.e. manufacturers, distributors, pharmacies, solution providers, etc.) so that multiple perspectives were represented at each table. Each table individually discussed three topics: Interoperability, Authentication, and Data Management, and then shared comments with the entire group of workshop participants. A final discussion topic, "Workshop Outputs", gave participants an opportunity to summarize their individual perspectives and comment on system implementation.

OVERARCHING THEMES – WHAT FDA HEARD

Over the course of two days and four discussion sessions, a number of recurring themes arose. These messages were prevalent throughout the sessions and were not necessarily associated with a particular sector of the supply chain.

1. FDA should focus on developing the functional requirements of the track and trace system

Overall, workshop participants were pleased that FDA shared system goals and potential system attributes as it enabled the opportunity to react to the agency's current considerations. Participants in general wanted FDA to focus on clearly defining the functional requirements of a track and trace system, including specifics requirements for data to be captured and how to authenticate packages. Participants in general did not believe that FDA should determine how the industry would meet these requirements, suggesting that this should be addressed through private sector solutions.

2. FDA has the opportunity to take a leadership role in standards development and implementation

Participants expressed that leadership and involvement from FDA would be beneficial in a number of areas:

- **Harmonization of track and trace standards:** Harmonization domestically would overcome any difficulties posed by the varying state requirements. Also international harmonization would help to support the global market.
- **Product scope:** Participants would look to FDA to determine the scope of products to be included in a track and trace system. Several participants suggested a risk-based approach for determining which products should be included. Some suggested that certain products (such as blood product and medical gases) be considered for exclusion from a track and trace system or whether existing practices for those products are adequate..

- **Participant validation:** Current challenges due to different levels of regulation and licensing could be avoided if a single regulatory body performed participant validation. Some participants suggested the Drug Enforcement Administration (DEA) model.¹

3. Explain the Public Health and Public Policy Case for Track and Trace

Many participants expressed the need to better understand the public health and public policy justification and benefits of using a track and trace system, to bring about change within their companies, their plants, and their leadership. Participants suggested a variety of ways in which the public health benefits of a track and trace system might be communicated or demonstrated, including anecdotal case studies, pilots, and alignment with international efforts. Many participants felt that more data were needed to support the public health benefits, and expected the FDA to drive the development of such data.

4. Incentivize adoption

Many of the participants acknowledged the effort and investment it would cost organizations to implement track and trace systems. Absent a requirement to implement track and trace, many questioned whether their organization would implement track and trace initiatives. While some participants understand that some financial and brand protection benefit would be realized (e.g. potential theft reduction, inventory optimization, recall management), many felt the return on investment was low. In order to balance this, participants wanted to explore ways to manage these costs.

To expedite adoption, some approaches suggested include:

- Impose penalties for those who were non-compliant;
- Link reimbursement/payment, from Medicare and/or Medicaid for example, with authentication of packages (Some pharmacy participants expressed concern with this approach as it could further reduce pharmacy margins.); and
- Fund through public or consortium-based private groups to support pilots and/or rollout measures

In addition, participants acknowledged that once some stakeholders adopted track and trace initiatives, these actions may incentivize other stakeholders to also move towards adoption.

5. Need for timely action

Participants sought timely guidance from FDA to establish national standards for track and trace prior to the requirements to comply with California's legislation in 2015. While recognizing that implementation would likely take several years, participants urged FDA to act quickly to set initial guidance so that companies can avoid duplicating existing systems efforts or avoid investing in systems that may become obsolete.

DISCUSSION TOPICS – HIGHLIGHTS

INTEROPERABILITY

Use and build upon current standards

Many participants highlighted GS1 standards in existing systems, both domestically and in several European countries. Some participants suggested that Health Industry Business Communications Council (HIBCC) and other standards be considered before determining a single standard. Some representing medical gas suppliers and blood centers questioned whether they would be obligated to change the current standards used for their products.

Interoperability will provide the basis of the authentication and validation of packages

Interoperability would make it easier to create compatible systems across geographies, product lines, and/or technologies.

Methods to ensure interoperability compliance

Fines for lack of compliance were suggested to incentivize interoperability. Many voiced concern about the potential impact on business operations and movement of drugs if delays occurred due to the authentication and track and trace system processing. Some participants noted that interoperability in other industries has been achieved through government regulations.

Impact on small businesses

Due to the potential cost and implementation burden, some participants from smaller entities wanted to explore solutions for leveraging a larger entity's system or solutions whereby small entities could benefit if all participants were part of a larger system.

Defining standard operating procedures for exceptions handling

Some participants noted that defining standard operating procedures would help to ensure that all participants who observe the same events use the same procedures. (Examples of events include: what to do when authentication fails, how to dispose of packages deemed 'suspicious', what type of reporting and alerts would be completed if a package was flagged.) Some participants also proposed an "exceptions-based" system, which would treat flagged suspicious packages as the exception. In this system, data for all products would still be collected, but detailed information about the distribution history would only be queried for those exceptions under investigation, to minimize cost and transactions.

AUTHENTICATION**Need for a specific definition of authentication and its requirements**

Authentication was defined for the purposes of this workshop as involving verifying that a standardized numerical identification (SNI)² is a valid number for the package with which it is associated and verifying that the package was sold, purchased, traded, delivered, handled, stored, brokered by, or otherwise transferred from legitimate supply chain participants, and confirming that there are no discrepancies in the distribution history. Participants expressed a desire for a more specific description of authentication, including more detailed information about how data transactions and databases would be utilized for these processes. Participants desired more clarity about what constitutes "authentication of the distribution history" and precisely where authentication would occur in the supply chain. The issue of who would be responsible if a product could not be authenticated (the sender, the recipient, or the system) was raised. Some participants suggested that authentication need not be performed at every step in the supply chain. Others suggested that authentication be performed only on products with the greatest risk of being counterfeited (as determined by FDA or an industry consortium).

Identification and validation of participants to be managed centrally

Participants were concerned about how they would recognize and validate their trading partners. Since trading partners and other supply chain participants are currently regulated at various state and federal levels, some participants suggested FDA could play a role in developing a centralized registration database, similar to the DEA model. The database could be designed to merge existing records from current licensing/registration databases. Participants acknowledged that some of the trade associations and licensing boards may see this as a challenge to their function or authority. An alternative perspective raised by other participants explained that they had trusted relationships with their suppliers and those with whom they traded, and viewed the current relationship as self-policing. Therefore, in their view, validation of trading partners may not be necessary for a track and trace system.

Additional direction on inference, aggregation and exceptions handling

The following topics were raised but not discussed in detail.

- **Inference**

Some participants stated that they rely on inference to efficiently process large amounts of inventory and distribute it. They believe it minimizes the risk of security breaches, by keeping the cases or pallets sealed.

- **Aggregation**

Aggregation, involving linking of SNIs of individual packages to a unique identifier at the case and/or pallet level, was viewed by some participants as one of the greatest costs for a manufacturer, due to the costs of optimizing the process and accounting for disruptions in the aggregation process (for example, caused by damaged data carriers or damaged packages).

- **Exceptions Handling**

Some participants expressed a need for explicit directions on standard operating procedures for handling authentication failures (examples: system or database failure, valid number but mismatched product information).

DATA MANAGEMENT

System design

Participants expressed that having a clear set of system requirements was far more important than FDA determining the design of the information technology (IT) infrastructure itself. While the audience appreciated having models to which to react, many felt that the design of system architecture should be left to data systems experts, and many participants stated a solution provider would be able to design a system that would meet FDA requirements.

A **centralized system** was viewed as attractive for several reasons. While concerned about confidentiality, participants recognized the value of having all data in a single database for regulatory purposes and for easily enabling interoperability. However, the fear of a single point of failure overshadowed the interoperability and regulatory benefits for some. Additionally, some people felt a single entity providing this service would lead to monopolistic behavior. Several participants raised concerns that they would be uncomfortable not having a choice as to how and where their data is stored.

A **decentralized system** was viewed as a positive option by some participants because of the ability for each player to maintain their own data. However, there was concern that if a major participant database went down (e.g., a large distributor), its effects could be similar to that of a centralized system failure. Interoperability was also a concern given the number of individual databases that would need to be able to communicate.

Most participants seemed to respond well to a **semi-centralized system**. Participants stated that such a system introduced price and service competition while maintaining many benefits of the centralized model. Participants liked having an option to choose a service provider and felt that their current provider may be able to support this effort and create continuity for their company. A balance between easy accessibility by regulators and dispersed risk of failure would need to be accomplished. Participants came up with a variety of hybrid ideas for data management, which would need to be explored by IT architects and system designers once the system requirements were clear.

Pilot and rollout perspectives

The idea of piloting a track and trace data management system was viewed positively by many participants. The idea to do a test-run prior to a full-rollout was generally viewed as useful to discover and fix major issues prior to nation-wide rollout. In addition, some felt that we might learn more about the public health benefits of a track and trace system from the data captured through pilots. Several ways were proposed to do a pilot, including:

Start with the basics and build in complexity over time

The model would start by requiring all supply chain participants to capture their own data only, and at a later date, supply chain participants would be required to upload other data related to movement and handling of the package. Then at a subsequent date, the supply chain would be required to authenticate the number. Workshop participants felt that this model would require similar upfront investment from all supply chain participants.

Start with a simple set of products and a select set of participants

This model would involve working with industry volunteers throughout the supply chain with a limited scope of products to test any data capture or sharing issues, before broadening to other products.

Start with a 'bookend' approach and phase in remaining players

The model proposed would not provide full visibility of the supply chain initially as it would start with manufacturers and pharmacies, and bring in distributors and logistics providers over time.

Participants felt that this model would simplify data management concerns by reducing the volume of data transactions.

A few participants advocated against having a pilot. These participants felt that proof-of-concept already exists in other countries, like Belgium and Italy, and felt that a pilot would only prolong real implementation.

Data visibility concerns

Many participants were concerned with maintaining business confidentiality throughout the supply chain. Some participants did not think that even FDA itself needs full visibility into the supply chain in order to serve the purposes of investigation, recall, and auditing or other public health purposes. Once FDA defined what data it needs or wants to access itself, or to have supply chain participants access for these purposes, many participants felt that their database managers and solution providers could resolve how to protect the data to permit this access while maintaining confidentiality of business transactions, rather than having all of the data fully visible to everyone in the supply chain.

Additional definitions needed on product status, alerts, and recalls

The participants expressed a desire for greater clarity on several aspects of data management. There were requests for anecdotal or case-study highlights on how alerts and recalls would function in a track and trace system. Other comments included:

Product status

The ability to have a 'live' field instead of static fields was considered useful, but questions were raised about how the field would be updated and by whom.

Alerts

The ability to flag SNIs based on batch number, date, or site produced was viewed as potentially helpful. Many suggested simple solutions, such as a coloring system in a pharmacy database (e.g. yellow for a product alert, black for a black label warning, etc).

Recalls

Having the capacity to facilitate recalls was seen as a considerable benefit. It was suggested that only manufacturers and FDA have access to this ability, given that the manufacturers handle their own recalls. However, more guidance was requested on how FDA would work with participants in recall situations.

Leadership in systems harmonization and participant needs

Participants expressed the need for a single unified standard to avoid having to comply with different state systems or requirements, and the preference to have harmonization with international systems if possible. Many felt that only through an overarching entity (like FDA) could a single standardized system be supported by supply chain stakeholders.

WORKSHOP OUTPUT

The topics discussed during the Workshop Output session were often continuations of earlier topics. Below is a summary of Workshop Output comments, including some that may also be mentioned in the above sections.

Ideas to ensure faster acceptance and implementation

- Use and build on existing standards being used in other systems
- Set a specific timeline
- Link reimbursement with adoption
- Encourage compliance through a combination of incentives and penalties
- Build consensus with foreign regulators
- Build stronger public health case
- Jointly fund a pilot or establish an industry consortium to support phase-ins or pilots
- Build an industry consortium to encourage constant innovation and evaluation of system
- Develop business opportunities for smaller players that may experience negative impact
- Explore an “exceptions-based” system to minimize system demands for data transactions
- Create alignment and involvement with state boards of pharmacy
- Maintain momentum with future workshops/meetings

Reasonable timeframe and rollout

Two comments were heard related to timeframe and rollout:

- the need to address timeframe prior to when California’s legislation is implemented in 2015
- interest in FDA leadership on requirements that would be the foundation of the system in order for companies to start adoption

Participants expressed differing views on how to determine the appropriate timeframe and develop a rollout plan. Some participants wanting a pilot felt comfortable with a shortened trial provided it was relatively successful and the major concerns were corrected prior to full roll-out. Time frames suggested for a pilot ranged from 6 months to 3 years.

With regards to full-scale rollout, several people referenced European programs that had run for many years prior to working smoothly. Others felt that with a good pilot and the use of clear standards, it could require less time to perfect (e.g. 2-5 years). Participants reflected on the individual challenges specific to their role in the supply chain, such as taking a line off of production to install serialization technology (manufacturing) or re-designing the sorting process (distribution).

Some participants thought a pilot was unnecessary and argued that proof-of-concept already exists. Some people thought it might take significantly longer to have a full system up and running given the complexity of these databases and transactions (e.g. upwards of 10 years).

Common concerns

The workshop also served as an opportunity for participants to express their other concerns (in no particular order) about:

- Costs to, and resources needed by, companies to establish a track and trace system
- Ensuring that all supply chain participants fully implement a track and trace system
- Ensuring the ability to incorporate future needs
- Loss of company efficiency during initial implementation
- Ensuring security of system data
- Ensuring reliability and accuracy of the system
- Ability of the system to solve some issues with counterfeits, rogue pharmacies and Internet operations

¹ The DEA model requires that all parties handling a controlled substance register with the DEA. Upon registration they receive a license to handle controlled substances. This license can be revoked at any time by the DEA. This system helps track participants involved in these systems.

² The SNI has been described in FDA Guidance for Industry: Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages (2010). Available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf>