

The Healthcare Industry's Business Requirements
For
Electronic Track and Trace
(An anti-counterfeiting strategy)

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The Product Safety Task Force
(PSTF)

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This PSTF document stands as the consensus work of an industry coalition, with representation and participation from throughout the healthcare industry. Please see below for an explanation of the PSTF goal and composition of the task force.

Table of Contents:

Executive Summary

PSTF Goal and Introduction

Technology Migration Path – Macro View

Implementation Issues and Next Steps – Micro View

Recommendations and Path Forward

PSTF Participant Organizations

Executive Summary

The Product Safety Task Force (PSTF) convened in order to assess technological approaches to combating the existence of counterfeit activity in the healthcare industry, specifically in pharmaceuticals. Early in the process, the PSTF determined that the adoption of an electronic track-and-trace system would enable the greatest supply chain security. Such a system can provide product authentication to the item level, delivered with less human intervention and interpretation than other anti-counterfeiting strategies reviewed. It also can provide other patient safety benefits, as well as operational benefits for logistics applications.

The PSTF proceeded to develop the business requirements necessary to allow for the development and implementation of an electronic track-and-trace system. The goal was determined to be item level Radio Frequency Identification (RFID) tagging for all products in the supply chain. This, coupled with a unique, serialized numbering system and “real-time” access to item level product data, would provide greater product protection. It is acknowledged that technologies other than RFID can provide unique identification, and that other factors may drive the decision to utilize this or other technology applications for some products, particularly for those for which counterfeiting is not encountered.

The PSTF asserts that the enabling data is perhaps the most critical component of the track-and-trace system, and actually drives or affects many of the other technical and business requirements of the system. The contents of the item-level data (e.g. the data needed for authentication and rules for data access and sharing) are therefore essential issues to be resolved early by industry stakeholders in a collaborative forum. Further, while the technology and supporting standards are currently under development, the data-related infrastructure is seen to be perhaps the most significant technical component on the road to implementation.

In order to resolve this and numerous other business requirements issues in a timely manner, the PSTF makes one primary recommendation: that greater collaboration and participation is required in order to deliver the track-and-trace system that is envisioned. Primarily as an offshoot of the PSTF process, it was determined that 1) there is a significant amount of work to be done to realize the goal; 2) the healthcare industry has some specific requirements for track and trace that differentiate the needed technological applications from those seen in other industries; 3) the publication of these industry-specific requirements will guide and influence the priorities of vendor and academic research & development efforts; and 4) there needs to be industry-wide participation in order to deliver such a collaborative and paradigm-changing technology.

Specifically, the PSTF proposes the need for a steering committee that would oversee sub-committees focused on specific issues in the areas of technology, implementation and business processes. The steering committee would consist of appropriate industry representatives with technical expertise as well as “sector reach” significant enough to affect wide-scale change and support. Sub-groups would contain representatives from throughout industry with specific expertise and interest in delivering key components of the track-and-trace system envisioned for reducing the incidence of counterfeiting.

The PSTF recognizes there are other similar exploratory initiatives, both public and private, where standards are being developed and research and piloting are being done, both within healthcare and without. The PSTF does not intend to duplicate any effort,

but instead supplement industry's critical efforts by ensuring that full participation and collaboration are achieved, thus bringing the most well-designed system to the implementation stage as quickly and as seamlessly as possible. As such, PSTF will help to facilitate a first meeting of particular industry trade groups and will observe the progress made by the industry towards the goal of item-level track and trace.

Product Safety Task Force Goal

To enhance patient safety by defining the requirements for the development and widespread adoption of an electronic track-and-trace system, thereby securing the drug supply chain, assuring drug product integrity, and reducing the incidence of counterfeit drugs.

Introduction

The Product Safety Task Force (PSTF) is an industry-wide coalition convened in September 2003 to discuss and make recommendations on technology-based strategies in parallel with the FDA's anti-counterfeiting initiative. The PSTF, facilitated by the Healthcare Distribution Management Association (HDMA), represents many sectors of the healthcare supply chain, including packaging suppliers, manufacturing, repackaging, distribution, group purchasing organizations, pharmacy, industry associations, and solution providers.

The group issued comments to the FDA in the fall of 2003 in response to the FDA Interim Report on Counterfeiting. These comments, which described the PSTF's "multi-pronged approach", can be found on the HDMA Web site at www.healthcaredistribution.org. The document includes discussion on authentication technologies (covert, overt and forensic methods) as well as licensing, business practices and enforcement, all issues considered essential by PSTF in thwarting counterfeiting.

However, the group decided early on that the most promising approach for reducing the incidence of counterfeit was implementation of an electronic track-and-trace system throughout the drug supply system. Following submission of its comments to the FDA, the PSTF set about defining the business requirements that would allow such a system to be adopted in the healthcare industry. What follows is the PSTF summary of the business requirements, issues to be resolved in implementing electronic track and trace, and the next steps required for industry.

Technology Migration Path – Macro View

The PSTF found that the greatest benefit to patient safety would be achieved by adoption of Radio Frequency Identification (RFID) for all products at the item level. The overall goal of the PSTF is to define the discrete steps needed to achieve this goal.

The key attribute of an electronic track-and-trace system is mass serialization at the item level. Serialized product "license plates" provide for unique identification of individual products at all points in the supply chain. Unique identification allows for product authentication, as items potentially can be traced to all handling points, including the point of manufacture, in order to verify authenticity. Thus, the authenticating data and the network that allows it to be shared are actually as critical as the enabling technology.

While the PSTF strongly supports item-level RFID as the ultimate goal, it is important to realize the migration path may include the use of serialized “bar codes” at least as an interim step, a concept that should be discussed by industry during track and trace standardization and collaboration initiatives.

The Task Force believes the following direct and indirect benefits will be achieved through a robust electronic track-and-trace system, particularly an RFID-based item-level system:

- Product authentication at all supply chain nodes and at all packaging levels
- Generation of an electronic pedigree capable of tracing product movement
- Significant patient safety benefits
 - Multiple pre-dispensing checks
 - Environmental exposure monitoring and reporting for products
 - Location applications in institutional and pharmacy settings (i.e. ability to easily and specifically locate products, equipment, etc.)
- Improved recalls and returns management
- Point of Sale (POS) – scanning of items at checkout
- Inventory and logistics enhancements
 - Stream-line receiving, put-away, picking, inventory, shipping, manifesting, transportation, ordering, returns
 - Labor savings for all parties
- Theft prevention (use as EAS tags)
- Better forecasting and production planning

The PSTF defines the migration timeline as having five “Phases.” The final phase is the full realization of benefits from item-level RFID deployment. This approach is similar to that identified in the FDA’s Final Report on Combating Counterfeit Drugs (February 2004). However, the PSTF believes that while the logistics level is a necessary starting point, it is essential to provide item-level serialization as quickly as practical in order to thwart counterfeiting. This can be accomplished by beginning item-level serialization on products at high risk of counterfeiting. This will provide a significant benefit to industry, as development and preparation would be centered on known products and deployment would become fully collaborative. However, this approach might require more immediate action from some supply chain members than others. Supply chain partners and other interested parties should identify the products that should receive earliest attention. A possible starting point for industry collaboration on this topic could include current state and NABP susceptible product lists.

The five Phases are detailed below, with significant attributes of each phase noted. It is difficult to assign actual dates to the timeline, as it is contingent on the accomplishment of certain technological, standardization, commercialization and collaboration requirements. While the date-specific goals set forth by HDMA and the FDA are desirable targets, it seems there are few options outside of such a phased approach, as detailed below. Since there is much to be done in developing the needed track-and-trace system, PSTF will maintain its focus on determining the technological migration path rather than predicting future milestones.

- **Phase 0: Current State**
 - Some pilots underway testing various applications, functionality, packaging levels, etc.;
 - Very few truly public trials, with very limited proven return on investment (ROI) from use cases;
 - Significant work to be done on technical matters related to system infrastructure, hardware, middleware, software, tag frequencies, readers, standardization;
 - Tag costs are above target for most potential users.

- **Phase I: Case and Pallet**
 - Significant utilization of track and trace for pallets and cases – primarily as a logistics application;
 - Provides experience using serialization;
 - Provides some ROI for logistics operations;
 - Allows authentication and validation of product to the case level, *with track and trace-enabled supply chain members*.

- **Phase II: Item-Level – some products**
 - Nearly full-industry utilization of track and trace for pallets and cases;
 - Nearly all manufacturers and distributors are track and trace-enabled for case and pallet, some use at pharmacies;
 - Deployed utilization of serialization for some products at item-level (possibly products at high risk of counterfeit);
 - Ability to authenticate product at item level by some supply chain participants;
 - Provides experience using track and trace at item level;
 - Provides nearly full ROI for logistics operations;
 - Allows authentication and validation of product to the case level nearly throughout the distribution channel.

- **Phase III: Item-Level – “all” products**
 - All achievements and deployment as mentioned above, plus
 - Nearly full industry provision of serialized identifiers at item level, by product / packaging originators, where deemed appropriate and feasible;
 - Ability to interact / operate at item-level, especially to authenticate product, in effect at most supply chain participants;
 - Significant use at pharmacies for receiving applications leading to authentication at point of receipt;
 - Provides opportunity to authenticate and validate product at nearly all packaging levels and nearly all nodes in the supply chain;
 - Provides ability to develop applications and systems that will deliver many of the significant patient safety benefits detailed above.

- **Phase IV: Item-Level – full utilization**
 - All achievements and deployment as mentioned above, plus
 - Full-industry provision of serialized identifiers at item level, by product / packaging originators, where deemed appropriate and feasible;
 - Ability to interact / operate at item level, especially to authenticate product, in effect at all supply chain participants;

- Full use at pharmacies for receiving applications leading to authentication at point of receipt;
- Ability to utilize all benefits and applications enabled via adoption of mass serialization, as noted above (such as patient safety, logistics, POS, theft, recalls, and returns).

Implementation Issues and Next Steps – Micro View

Although the high-level migration path has been detailed above, the PSTF outlined a number of critical issues that must be addressed in order to realize the ultimate goal. These issues are spelled out briefly below, with greater discussion on particular topics later in this document. There may be debate about certain issues, but the point of the PSTF's findings is to spur expanded discussion, development and agreement in order to bring about a fully-standardized and adopted system for track and trace.

The PSTF categorized the issues into the following sections: Technology, Implementation, Business Processes, and Governance. There is considerable and recognized overlap and interdependencies when assessing the issues and categories. Initially, this document will define the issues; the action plan for resolving the issues and delivering a system for track and trace functionality are also outlined below.

Note: an * (asterisk) indicates that, per the PSTF, the issue(s) is one of high priority, and must be resolved concurrently with other high-priority items prior to follow-on issues. These issues must be resolved in the relatively near term.

Technology

- *Database Architecture
 - How the track-and-trace-enabling database is constructed.
 - Verisign has been selected by EPCglobal to run the EPC Directory, but decisions must be made on where the critical track-and-trace-enabling data is located – i.e. in distributed databases, or in a central location for essential tracing information storage and access, etc.
 - These decisions will be governed in part by industry decisions on data-related topics in Implementation and Business Processes below.
- *Hardware Performance and Interoperability
 - Required hardware components and related issues from a technical standpoint need to be defined – operational ranges, applicability and durability for all participants in supply chain.
 - Global standards are needed that will ensure interoperability and set minimum performance criteria for tags, readers, operating frequencies, communication protocols.
 - Testing and qualification procedures must address acceptable failure rates, reliability issues, and interference with pre-existing wireless systems.
 - Needed technical performance capabilities will be impacted significantly by some of the decisions on Implementation topics and vice versa.
- *Frequency
 - Radio Frequency (RF) issues specific to interoperability in supply chain environment – especially interference and collision in hospital environment, among others.

- Tag and reader frequencies and possible interference issues.
- Performance issues such as the ability to read through liquids and metals.
- Global standardization around frequencies, both within healthcare and in parallel with other industries.
- Connection between technical frequency issues and Business Process and Implementation issues (especially consumer privacy).
- Data Security (Accessibility)
 - The method by which data will be secured to prevent access from unauthorized entities.
 - Data authentication and a network-driven “alerting” mechanism must be considered as essential components when utilizing the technology as an anti-counterfeiting application.
- Form of Tag (Tag Type)
 - The capabilities (pros and cons) of various tags must be determined and defined.
 - Guidance must be developed to examine how different types of tags meet the special needs of the healthcare industry (i.e. tag size, cost, security and authentication, read/write, etc.).
 - Potential ramifications of tag choice must be examined.
- Systems Redundancy (Business Continuity)
 - Complete, instantaneous, invisible redundancy must be enabled.
- Licensing/Identifier Allocation
 - The process for control and assignment of serialized identifiers must be defined and standardized, considering issues such as eventual reuse as well as encoding, securing and/or encrypting the identifiers.

Implementation

- *Product Stability Testing (manufacturing sector to resolve with FDA)
 - Resolve the process to be followed in determining whether and how stability testing is needed in order to allow pilots and eventual deployments to proceed.
 - FDA is considering how to proceed.
 - PhRMA is preparing recommendations.
- *Packaging Hierarchy
 - The method for determining how packaging levels are to be identified, must be defined, both in terms of the serialized identifiers themselves as well as the relational (linking) requirements to allow for aggregation of items to a case, for instance.
- *Data Synchronization
 - Facilitating the common use of data standards, specifically in how product identities, characteristics, and other critical items are transmitted, shared, and stored.
 - Development of the system to support rapid exchange of a common data “language” is critical to the adoption of item-level track and trace.
- *Migration Path Strategy Collaboration
 - Need a shared strategy for how industry plans to use the technology and spin-off applications and benefits.

- Use of existing technologies (bar codes, data exchange protocols, networks, and systems, etc.) as interim and permanent solutions must be discussed.
- Collaboration on how to begin item-level RFID tagging, including possible selection of a list of products at elevated risk for counterfeiting.
- Determination of a migration strategy will allow potential suppliers to provide the solutions needed.
- *Public Relations/Privacy
 - A comprehensive plan must be developed with stakeholders and initiated early on in order to successfully convey the patient safety benefits of the planned use of technology, as well as the consumer/patient privacy steps that are now in place (HIPAA) and those that will be taken in the future.
- Tag Application
 - The party or the supply chain segment that applies the tag should be determined, both for the interim and long term.
 - Generally agreed from an anti-counterfeiting standpoint that the safest location for this task is likely at the manufacturer / repackager – this likely is also the most efficient location.
 - Tag application impact on packaging, consumer privacy and notification, and packaging production line speeds needs to be studied.
 - Tag placement standardization necessary for location within label and/or on package, case, and pallet.
 - Regulatory implications for labeling and tag placement must be considered.

Business Processes

- *Tag Data Standard – Structure
 - Industry must decide whether serialized numbers are assigned as random identifiers or if they be based on the NDC, for example.
 - The important and various industry uses of the NDC number which are connected to current bar code scans need to be considered.
 - Determination of “mission critical” data to be carried on the tag versus in a reference database(s) needs to be determined.
- *Data Ownership and Sharing
 - Industry must identify data critical to enabling track and trace.
 - Industry must determine what other business data is needed and what is to be made available.
 - Rules for sharing, ownership, and access are some of the most critical issues to be resolved in order to implement the technology, both from an authentication standpoint and a business process (trading partner collaboration) perspective.
 - Decisions here link into Implementation and Technology decisions on data synchronization and what is possible and most effective for database architecture, respectively.
- Validation (Process and Computer System)
 - The industry needs assurance that the track-and-trace system is functioning properly, both prior to deployment and proactively after implementation.

- Possible regulatory involvement from a validation standpoint must be considered.
- Reporting Requirements
 - Regulatory issues need to be evaluated.
- Stakeholder Issues – Examples:
 - The existence of multiple reader types in the supply chain and in retail and hospital pharmacy (bar codes, various radio frequencies).
 - RFID and bar coding issues in hospitals (interference, integration, cost, installed base or lack thereof, FDA and JCAHO standards).
- Data Archiving
 - Industry needs to determine when, or if, to close out serial identifiers.
 - Rules for archiving – how, where, access, length of storage – must be created.
 - These decisions will connect to others regarding when identifiers can be reused in the industry.
- Track and Trace Process Model
 - Industry needs to determine what must happen at each point in the supply chain between trading partners. Industry also must determine the desirable or possible scenarios.
 - Contingency planning/modeling must be done for a number of these scenarios (e.g. what should happen in the event of a network outage, loss of access to the database, or an unsuccessful tag read. How will stakeholders know when a tag scan is missed?).
 - Industry needs to determine how to handle process exceptions (detection of potential counterfeit product, recovery of units that could not be authenticated or other “out-of-norm” process-oriented events).
- Tag Disablement Questions/Rules
 - Industry needs to determine how, when, where and why to disable tags. Rules to govern behavior should be considered.
 - Must determine the pros and cons of tag disablement, and compensation structures for either choice.
 - Options for disabling and other alternatives should be considered.
- Tag Tracing
 - Industry must determine how tag tracing is to be done and the impact on operations and trade relations.
- Tagging Decision Criteria
 - Must determine the products that do and do not get tagged as well as the person or entity that should be entrusted with that decision-making authority.
 - General industry agreement on the necessity for tags versus bar codes, versus no use of the technology may be needed to smooth adoption of the system.

Governance

- Global Issues – Standards, Cross-Border Issues (Flow of Goods)
 - Interoperability across geographies and industries where differing standards, languages, regulations, and frequencies must be considered.
 - Consult the Drive Project in Italy, where a mass serialization mandate was enacted in healthcare.

- Industry Group Continuity and Coordination
 - Need consistency, collaboration, and connection to and among various entities working on similar technology and adoption in order to move toward the best “global solution” with greatest speed and best implementation plan.
- Regulatory Implications
 - Agency interactions on reporting requirements and guidance on proper use of technology are needed.
 - Assess implications of many of the above issues (stability testing, system validation, labeling, and consumer privacy) and determine path forward to manage these issues effectively.

Recommendations and Path Forward

The previous outline describes the components and issues critical to providing a track-and-trace system for the healthcare industry. However, it also can serve as an industry guide and action plan for beginning the process of developing the system. The PSTF recommends a collaborative process be established whereby identified issues, such as those outlined previously, are discussed and resolved.

The PSTF finds value in creating a healthcare supply chain steering committee to coordinate the work of various sub-committees, to whom these issues and topics should be referred. The steering committee should consist of representatives from appropriate industry entities with the authority, business connections and knowledge to capably represent industry sectors and stakeholders. This group could partially consist of appropriate representatives from various industry associations, representing manufacturing, distribution, pharmacy in all its forms (retail, independent/community, institutional), and hospital IT management. Other important members of the steering committee should be standards and technical groups such as EPCglobal and the Auto-ID Labs, and possibly regulatory agencies such as the FDA.

The steering committee should form sub-committees to address the issues detailed in the Technology, Implementation and Business Processes sections of this paper. The steering committee should appoint representatives to the various subcommittees based on knowledge of appropriate individuals and organizations from across the industry. With equal and appropriate participation on each sub-committee, the essential issues would be discussed; priorities, timelines and deliverables established; and the groups’ essential issues resolved. The steering committee would oversee “cross-functional” issues; manage the process, deliverables, timelines and external liaisons; and maintain responsibility for overall collaboration, agreement and adoption throughout industry.

The PSTF fully recognizes the efforts already underway to create such a track-and-trace system and only recommends supplementing those efforts by enhancing development of issues and applications specific to the healthcare industry. Early work is taking place at EPCglobal and at the Auto-ID Labs. The concept developed by the Auto-ID Labs is being standardized and commercialized by EPCglobal. Further, various industry associations are working on adoption and/or exploration of this technology, led by HDMA’s publication of its EPC White Paper, *Protecting Safety and Improving Efficiencies in the Healthcare Supply Chain – Using Electronic Product Codes*, in November 2003. There is a need for greater collaboration across industry, but there is the possibility that some of these existing efforts could be utilized as a forum to resolve

the issues outlined previously. The PSTF does not advocate duplication of effort, but does recognize there is a need for greater participation from throughout the healthcare supply chain to develop the standards and foster adoption of this needed technology.

PSTF Participant Organizations

The appearance of an organization's name below indicates participation during the Product Safety Task Force process. Although individual views may differ with respect to the specific issues addressed herein, each of the participants does agree that: 1) an electronic track-and-trace system is one of the key strategies in the effort to reduce counterfeit drugs, and 2) to the extent allowed by law, that the healthcare supply chain needs to engage in increasingly more collaborative efforts to develop the system and drive adoption.

3M Pharmaceuticals
American Society of Health-System Pharmacists (ASHP)
Amerinet, Inc.
AmerisourceBergen Drug Corp.
AstraZeneca-US
Auto-ID Labs
Borschow Drug
Cardan Technologies
Cardinal Health, Inc.
Centocor, Inc. (a division of Johnson & Johnson Pharmaceuticals)
Eli Lilly & Company
GlaxoSmithKline
Generic Pharmaceutical Association (GPhA)
Healthcare Distribution Management Association (HDMA)
Health Industry Group Purchasing Association (HIGPA)
Henry Schein, Inc.
Kerr Group, Inc.
MeadWestvaco Corporation
Merck & Co., Inc.
McKesson Supply Solutions
National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)
Owens-Illinois, Inc.
Pfizer US Pharmaceutical Group
Pharmaceutical Research and Manufacturers of America (PhRMA)
Procter & Gamble Pharmaceuticals, Inc.
RFapp Solutions LLC
Smith Drug Company
Supreme Distributors/Purity Wholesale Grocers