# A Solution for Pharmaceutical Track and Trace in the United States - Part 1

*This article is Part 1 of a four-part series on solving the Track-and-Trace requirements being faced by the participants in the US pharmaceutical supply chain. Part 1 describes current industry efforts to define a solution that meets both regulatory and business requirements. Part 2 provides a high-level description of a new solution that relies and leading edge technology that has been proven over ten years of rigorous practical use. Part 3 describes the step-by-step choreography of the new solution. Part 4 describes the characteristics of an Independent Administrator to oversee the solution on behalf of all stakeholders: industry and government, alike.*

The Drug Supply Chain Safety Act (DSCSA) mandates that members of the pharmaceutical supply chain need "to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States."[i] Specifically, DSCSA demands that a record be available for tracking the change of ownership from manufacturer to dispenser by 2023.

The FDA defines the requirements of this system as:

1. enable verification of the legitimacy of the drug product identifier down to the package level;
2. enhance detection and notification of Suspect products[ii] in the drug supply chain; and
3. facilitate more efficient recalls of drug products.[iii]

Of course, a solution to address these requirements needs to be feasible along three dimensions: Technical, Business, and Security.

In response, the pharmaceutical industry has comes up with a two-fold approach to addressing these requirements. The first element of the solution is the development of machine-readable labels for every salable package that include unique identifiers of the product, its manufacturer, its batch, and its creation date. This solution, referred to generally as "serialization" is costly to implement, but Business feasibility has been enhanced by offerings from repackagers which can provide serialized packaging cost-effectively -- even for small clients. It is also a straightforward Technical solution that lends itself to a wide array of implementations, many of which are being implemented today. And the various solutions available provide selectable levels of Security: mostly in the form of randomized serial numbers to keep counterfeiters from guessing legitimate values.

The second element of the solution, known as "track and trace," is a more vexing problem. In theory, it merely requires that all changes of ownership be reported to a single database. Such a Technical solution would facilitate tracking the dissemination of products as they propagate through the supply chain. It would allow purchasers to review the change of ownership of a product back to the manufacturer. As well, it would allow a manufacturer to see where all his product has gone (should he be required to recall a particular batch for safety reasons).

Unfortunately, this simple technical solution, does not conform to the Business objectives of most members of the supply chain. The pharmaceutical market is both large and highly competitive. And for competitive reasons, members of the supply chain are reticent to make public their sales figures, their sources, and their customers.

The industry has invested several years seeking to define a Technical solution that would meet the Business objectives of confidentiality. The high-level solution that is being formulated requires each member of the supply chain to maintain its own database that includes its sourcing of each product it purchases and its customers for each product it sells. This structure creates a complex web of data bases as simplified in Figure 1.

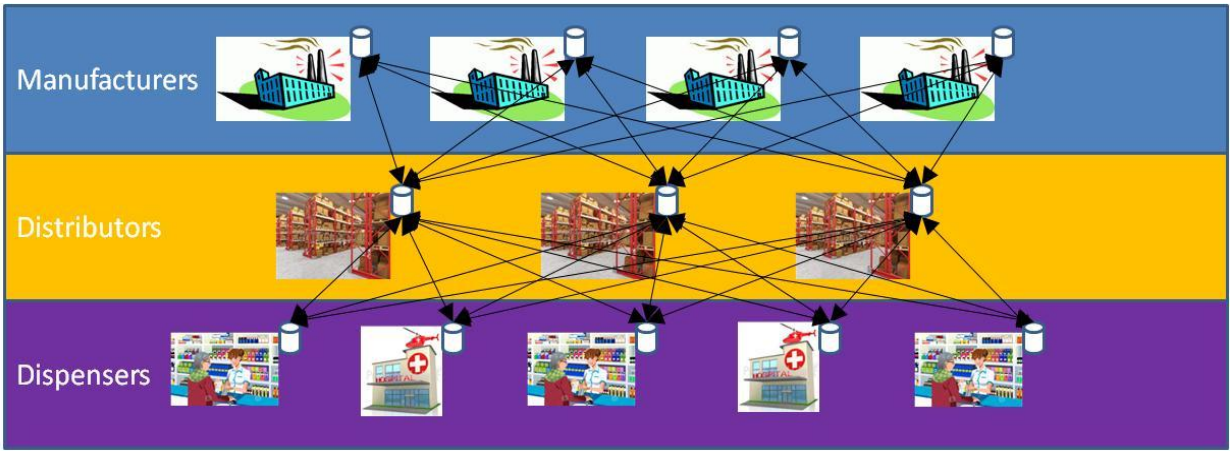


**Figure 1: Current Industry Solution: One solution that protects company proprietary data requires that each company maintain its own database of its suppliers and customers.**

This solution would then provide a mechanism for the FDA to track a package (using its serial number) from end to end by querying a manufacturer's database to find out which distributor they sold the product to. Then, in turn, the FDA would query the distributor's database to find out which dispenser they sold the product to. This achieves the desired result of supporting track and trace, while maintaining data confidentiality.

But while technically feasible, this solution is extremely cumbersome, vulnerable to attack, and expensive. It requires that every firm establish a query facility, to be used by the FDA, for its transaction data (likely housed in an ERP database that includes large amounts of other proprietary data) as depicted in Figure 2.

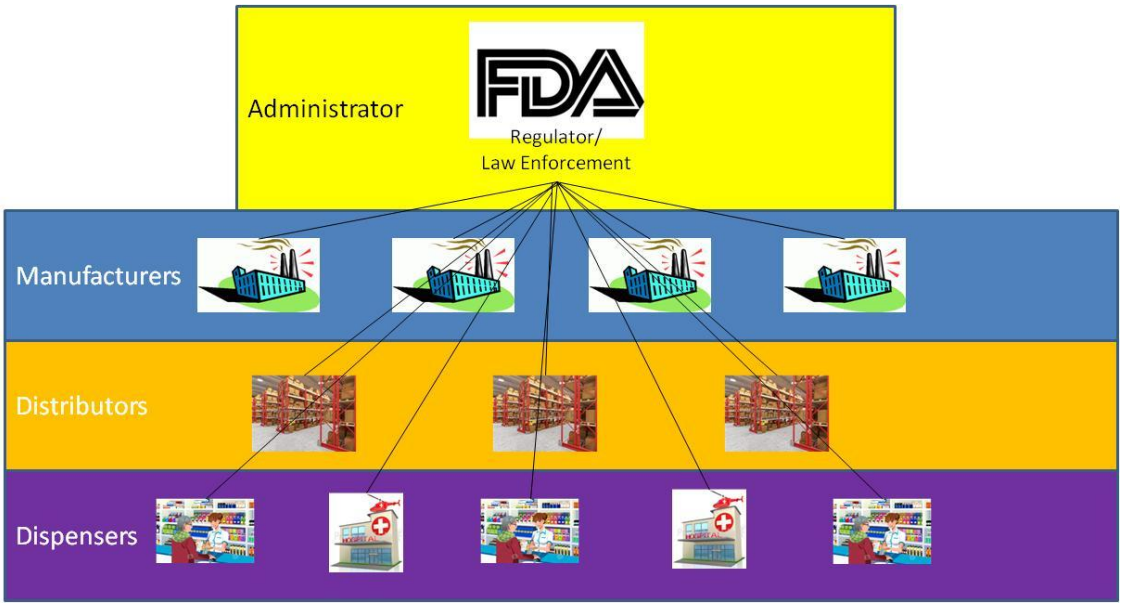


**Figure 2: The FDA would need access to each companies database and have to proceed in a stepwise fashion from one database to another to track a product through the supply chain.**

Furthermore, each firm would have to establish, manage, and maintain identification credentials for the regulators granted access to the database of all of its transactions. And because different firms will have different underlying databases (e.g., Oracle, SAP, IBM), different supply-chain-members will have difficulty trying to pool resources to create a consistent interface for the FDA to access their data. Add to this the complexity of internal maintenance schedules and other complexities that occur in trying to create a mash-up from thousands of different data sources, and the solution becomes untenable.

Table 1 lists the pros and cons of the currently envisioned industry solution.

**Table 1: Pros and Cons of Current Solution. The currently envisioned industry solution is complex and costly, but it's biggest shortcoming is its inability to dynamically identify a questionable transaction.**

| Category | Pros | Cons |
|---|---|---|
| **Technical Solution** | Supports the tracking of a product to its source to verify its provenance | **Does not allow for dynamic identification of questionable transactions** |
| | | System may have difficulty dealing with lack of certainty about which Serial Numbers are included in each carton, making the tracing of a particular package difficult |
| | Supports tracing of a product through the supply chain for purposes of recall | Tracing a product for recall can be time consuming, increasing the public exposure risk of a tainted product |
| | Maintains confidentiality of firm's | Integrating data from hundreds of |

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|---|---|---|
| | proprietary data | sources makes the process slow and cumbersome. |
| | | Conflicting maintenance schedules among the hundreds of participants will make data integration challenging |
| | Scalable to address more companies | Significant impact on complexity |
| | Scalable to address more products | |
| | Scalable to address more transactions | Some impact on performance |
| **Business Solution** | | Requires each firm to establish its own tracking database |
| | | Requires each firm to establish a vetting and access control mechanism for the database |
| | Firms control their costs | Cost will be high |
| | | Costs will be disproportionately high for small firms |
| **Security** | | Authorized agents (e.g., FDA) may need to obtain separate access credentials to access each of the hundreds of different databases |
| | Hacking resistance equal to other IT assets in each firm | Single implementation of each firm's database is vulnerable to hacking |
| | Collusion resistance subject to governance model employed by each firm for their database | Depending on database design, collusion may be hard to prevent |
| | Breach resistance equal to other IT assets in each firm | Depending on encryption practices, data may be vulnerable |

As can be seen from the table, the currently envisioned solution suffers from being complex and costly. But its most severe limitation is that it is unable to dynamically identify a questionable transaction. For example, if Distributor A purchases 100 units of Drug X from its manufacturer and then sells 40 units of the drug to Dispensers D, E, and F, it would appear that at least 20 of the units sold are questionable. They may be counterfeit, gray-market, or diluted product. But the system has no way of alerting the FDA (or law enforcement) that suspicious sales have taken place. Unless the FDA has a reason to look into the practices of Distributor A or a problem arises with the use of Drug X, there is no reason to investigate.

Distributor A could even take advantage of the inability of the manufacturer to accurately specify the exact serial numbers of the products it has shipped to Distributor A to create (or purchase) effective counterfeits. If the manufacturer certifies that the serial numbers in the five cartons of 20 that it shipped to Distributor A come from a list of 300 serial numbers used for its most recent batch of product, Distributor A could create labels for its counterfeit products that use legitimate serial numbers from the batch, further masking its counterfeiting activities.

In the next installment of this series we will review a solution that not only addresses the dynamic identification problem, but also provides a lower cost, higher reliability, and more secure solution to the track-and-trace problem.

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[i] http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/

[ii] *Suspect product* is defined in section 581(21) of the 53 FD&C Act as a product for which there is reason to believe it (A) is potentially counterfeit, 54 diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result 55 in serious adverse health consequences or death to humans; (C) is potentially the subject of a 56 fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would 57 result in serious adverse health consequences or death to humans.

[iii] Ibid