2016 WHITE PAPER

DSCSA
The Compliance Journey

Introduction

There's no question that the presence of counterfeit pharmaceuticals—in the health care supply chain and otherwise—is a very real issue. The World Health Organization reports that up to one in 10 drugs sold across the globe are fake. In some countries, the numbers may be as high as 50 percent.[1]

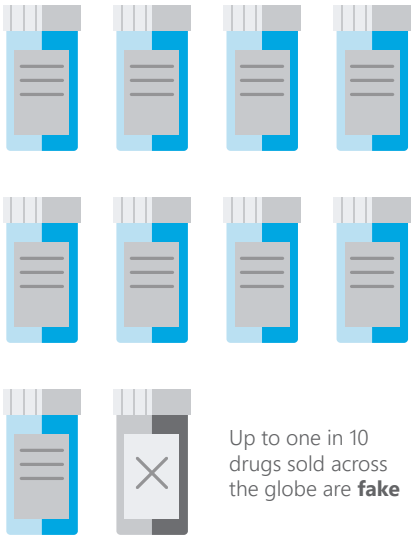
It would be too easy to assume the problems must be only in developing rather than industrialized nations. But roughly 85 percent of the world pharmaceutical market is in the developed world.[2]

In North America as elsewhere, fake medicines mean patients don't receive the help they need—or, worse yet, they receive substances that can worsen their conditions. In addition, counterfeit pharmaceuticals—an industry worth an estimated $200 billion worldwide[3] —waste consumer income and dampen the desire to invest in new research and development.

For those in operations management or wholesale distribution, the challenges only increase. The pressure to get things right—from both a liability and compliance standpoint—is higher than ever before.

Though the FDA has established a 10-year timeline for the process to be complete—with requirements that range from unique product identifiers on certain prescription drug packages to the tracing of who handles a drug each time it is sold in the US market—deadlines for certain components loom much closer.

In addition, the FDA is explicit in what must be done—but not how.



Up to one in 10 drugs sold across the globe are **fake**

In order to combat the challenges and consequences of counterfeit drugs, Congress enacted the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act, in 2013. Enforced by the US Food and Drug Administration (FDA), the goal is to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed across the country. The DSCSA deals specifically with prescription drugs; it does not apply to over the counter drugs, medical convenience kits or devices.

[1] "20 Shocking Counterfeit Drugs Statistics," HealthResearchFunding.org, December 2014. http://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/, accessed Sept. 12, 2016.

[2] Bale, Harvey. "Pharmaceutical Counterfeiting: Issues, Trends, Measurement," WIPO/OECD Workshop, 2005. http://www.oecd.org/sti/ind/35650404.pdf, accessed Sept. 12, 2016.

[3] "20 Shocking Counterfeit Drugs Statistics," HealthResearchFunding.org. http://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/, accessed Sept. 12, 2016.

DSCSA Past, Present—and Immediate Future

Individual states such as California began tackling the issue of counterfeit drugs more than a decade ago with early pedigree laws. Pedigrees are statements of origin for pharmaceuticals, and in electronic form, are known as ePedigrees. California's attempts at legislation in the area date back to 2004, with an initial effective date set for a few years later.

Eventually, efforts by various states were standardized under the Drug Quality and Security Act. Simultaneously, governing bodies in other parts of the world—Brazil, China, and the European Union, for example—began their own efforts. A key difference in other emerging "track-and-trace" strategies versus the work of the US FDA, however, is that other countries have chosen to create central cloud-based repositories of data for more efficient processes. The US legislation has no such component. Again, the emphasis has been on the what, but not the how.

The first deadlines related to the DSCSA—lot-level traceability—passed in January 2015. But full drug serialization is next.

By November 2017, the DSCSA requires that manufacturers (followed by repackagers a year later) use a unique product identifier on certain prescription drug packages. That identifier is to include a unique National Drug Code, serial number, lot number and expiration date.

Unless otherwise allowed by the FDA through guidance, that applicable data, by law, "shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package" and "shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case." Also: "verification of the product identifier may occur by using human-readable or machine-readable methods."[4]

By November 2019, wholesalers will only trade products with product identifiers; dispensers will do the same by November 2020.

This increasing volume of data will need to be handled in unprecedented ways. In addition, due to the lack of centralized data pool, the information will need to be communicated effectively and efficiently with each member of the supply chain. Having systems in place to process that level of data will require time for implementation, tests and tweaks.

By 2023, the traceability rules will apply at the unit level, rather than lot, going all the way back to initial manufacturer or repackager.

In the absence of detailed process instructions from the FDA, a number of standards for the exchange of product tracing information have been under development, including those from global standards organization GS1. The GS1standards are by far the most adopted, but aren't the only ones.[5]

Such standards are recommended practices for compliance, typically developed by working groups representing various aspects of the industry, but they're not mandatory.

It's important to note that the DSCSA as a whole is federal law, rather than a guideline. There will be penalties for non-compliance at every deadline step. Those penalties have not yet been officially stated, but could include fines, suspension/revocation of license and perhaps even imprisonment, according to industry experts.

The bigger picture, however, is that counterfeit pharmaceuticals cost more than technology upgrades or supply chain headaches. They cost lives. It is believed that between 100,000 and 1 million people die each year related to counterfeit drugs worldwide. The discrepancy in that scope is evidence of the need for better tracking and traceability; in 2015, researchers at the University of California, San Diego School of Medicine were surprised by "how little is known about the precise scope of the problem and how few mechanisms exist to monitor it despite the availability of some data," according to lead author Tim K. Mackey, MAS, PhD, assistant professor of anesthesiology and global public health, director of the Global Health Policy Institute and associate director of the joint master's program in health policy and law. "Nobody has a good idea how big the problem really is. There are guesses, but it's hard to get accurate statistics on a criminal activity of this magnitude."[6]

[4] "Title II of the Drug Quality and Security Act," U.S. Food and Drug Administration. http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm, accessed Sept. 21, 2016.

[5] "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information Guidance for Industry," US Food and Drug Administration, November 2014. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM424895.pdf, accessed Sept. 12, 2016.

[6] "Falsified Medicines Taint Global Supply," University of California, San Diego, press release, April 2015. http://www.eurekalert.org/pub_releases/2015-04/uoc--fmt041615.php, accessed Sept. 12, 2016.

Primary Suply Chain Stakeholders

MANUFACTURER

REPACKAGER

WHOLESALE DISTRIBUTOR

DISPENSER

2015

- **January :** Cannot accept product ownership without transaction history and statements (either paper or electronic) — DISPENSER
- **May:** Authorized trading partners only and systems in place for verification of suspect products — MANUFACTURER, REPACKAGER, WHOLESALE DISTRIBUTOR, DISPENSER
- **November:** Licensing standards for wholdesale drug distributors regulations — WHOLESALE DISTRIBUTOR
- **June :** Cannot accept product ownership without transaction history and statements (either paper or electronic) — DISPENSER
- **July:** Authorized trading partners only and systems in place for verification of suspect products — DISPENSER

2017

- Must accept and transfer product ownship electronically (e-pedigree) — MANUFACTURER, REPACKAGER, WHOLESALE DISTRIBUTOR
- **November:** Unique identifier on each package or honogeneous case* — MANUFACTURER

2018

- Cannot accept product ownership without transaction history and statements that are electronic) — MANUFACTURER
- **November:** Unique identifier on each package or honogeneous case* — REPACKAGER
- **November:** Transaction only with **serialized** products — REPACKAGER

2019

- Product identifier data retained for six years from transaction — REPACKAGER
- Records must be retained for six years from conclusions for investigation records; ongoing timelines, depending on transaction date — REPACKAGER
- Transaction history for saleable returned products/ subsequent purchasers/ stakeholders of products (lot level) must be retained for six years; ongoing timelines, depending on transaction date — WHOLESALE DISTRIBUTOR
- Records must be retained for six years from conclusions for investigation records; ongoing timelines, depending on transaction date — WHOLESALE DISTRIBUTOR
- **November:** Transaction only with **serialized** products — WHOLESALE DISTRIBUTOR

2020

- **November:** Transaction only with **serialized** products — DISPENSER

2021

- **November:** Interoperable systems for **package-level** traceability and drug distribution regulations — MANUFACTURER, REPACKAGER, WHOLESALE DISTRIBUTOR, DISPENSER

2023

- Expected operational **unit-level** electronic track-and-trace systems — MANUFACTURER, REPACKAGER, WHOLESALE DISTRIBUTOR, DISPENSER

* Must be 2D data matrix bar code; that is, serialization

Source: Gartner (July 2015)

Aggregation, Shipping Manifests and Individual Responsibilities

The DSCSA directly impacts manufacturers, repackagers, wholesale distributors and dispensers. But even now, there's some question about who might handle what portion of the requirements. Under the law, manufacturers are supposed to have pharmaceutical product labeled by the time it reaches another part of the supply chain; those numbers are then verified and tracked when received. The concept of aggregation would mean that the manufacturer would apply a sticker or barcode on the outside of the box or pallet that would aggregate information for all of the items as one unit. Obviously, it would be simpler for third-party logistics providers and wholesale distributors than having to check individual items. But as many as half of manufacturers are refusing to aggregate, placing the effort squarely on the shoulders of the downstream trading partners. They cite a variety of reasons, including substantial cost and effort.

The law does spell out some tasks. Among the key provisions, directly from the FDA:

PRODUCT IDENTIFICATION:

Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.

PRODUCT TRACING:

Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.

PRODUCT VERIFICATION:

Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.

DETECTION AND RESPONSE:

Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.

NOTIFICATION:

Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.

WHOLESALER LICENSING:

Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.

THIRD-PARTY LOGISTICS PROVIDER LICENSING:

Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license[7].

In terms of shipping and the 856 ship notice/manifest Electronic Data Interchange (EDI) transaction set, though guidance and regulations for implementing the DSCSA continue to evolve, the Healthcare Distribution Management Association has offered a voluntary "streamlined format" for the exchange of Transaction Information (TI), Transaction History (TH), and a possible Transaction Statement (TS).

[7] "Drug Supply Chain Security Act (DSCSA)," U.S. Food and Drug Administration. http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/, accessed Sept. 21, 2016.

Achieving Compliance

Gartner, in its 2015 analysis[8], "Assessment of Trace-and-Trace Serialization Legislation for Life Science Companies, United States," offered a number of recommendations for supply chain leaders responsible for meeting compliance. Among them:

PLAN

Plan now for 2017 compliance-based requirements. Assess broader supply chain implications, including monitoring emerging global legislation, standards and best practices.

INTEGRATE

Integrate DSCSA requirements into broader business continuity planning and risk management processes across your supply chain networks and impacted partners.

OPTIMIZE

Optimize the value of collaboration across impacted supply chin stakeholders for processes, systems, and change management initiatives and pilots.

"All supply chain stakeholders, including smaller distributors and dispensing retail pharmacies, must take responsibility for working across their supply chain partners to ensure they fully understand the compliance criteria and time frames," ***wrote analyst Andrew Stevens***. "Industry visibility of mandated requirements is broadening, as are the consequences of noncompliance to supply chain revenue streams and operations. Any delay from impacted stakeholders in assessing US requirements at the earliest opportunity could result in them, and the supply chains they are supporting, becoming nonoperational within the US—resulting in associated drug shortages."

Working toward compliance now will mean deploying resources, exploring the options, developing strategies—and, potentially, taking the lead with other members of the supply chain to be proactive about success.

Unique Device Identification (UDI)

Along with the DSCSA, the FDA also has been responsible for enforcement of the Unique Device Identification (UDI) legislation. UDIs assign unique identifiers to medical devices, and are intended to improve public safety, enhance the recall process and create efficiencies within the supply chain.

There are some similarities, but also differences.

"The UDI rule is a regulatory text developed by FDA staff under the authority of the Food and Drug Administration Amendments Act (FDAAA) of 2007—an act of Congress—while the DSCSA text is itself an act of Congress," reported ***HealthcarePackaging.com***. That difference will likely lead to differences in the way the FDA implements and enforces the two regulations. Because the FDA developed the text of the UDI regulation, the agency should have greater authority to make use of 'enforcement discretion' with parts that turn out to be unexpectedly and unnecessarily complex or difficult to implement. In contrast, the FDA may not have that same flexibility when it comes to implementing and enforcing the DSCSA, because the text was provided to it, as is, by Congress. There are no provisions that give the FDA discretion over its implementation beyond a few fixed exceptions and exemptions. For that reason, the FDA will likely feel bound to enforce even those provisions that are eventually found to be unnecessarily difficult."[9]

UDIs were required on some types of medical implants in 2014, expanding to all implants and all life-sustaining and life-supporting products. In 2016, Class II products are added to the list.

And there is one other key distinction: UDIs are identified with the assistance of a central repository; the Global UDI Database (GUDID) allows data to be shared securely.

[8] "Stevens, Andrew. "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, United States," April 29, 2106. https://www.gartner.com/doc/3301017/assessment-trackandtrace-serialization-legislation-life, accessed Sept. 21, 2016.

[9] Rodgers, Dirk. "UDI vs. the DSCSA," HealthcarePackaging.com, November 2014. http://www.healthcarepackaging.com/trends-and-issues/regulatory/udi-vs-dscsa, accessed Sept. 12, 2016.

In Search of the Ideal Solution

Overcoming the challenges of DSCSA compliance will take more than a wait-and-see approach. Operations management personnel, wholesale distributors and anyone else who understands the weight of the issue—and the opportunities innate in the ordeal—already are seeking strategic partners and platforms.

On their wish lists:

1.

Out-of-the-box software that will make it as painless as possible to manage unique identifiers prior to the November 2017 deadline.

2.

Expertise in the health care marketplace.

3.

True visibility and traceability of products throughout the supply chain.

4.

A platform that offers agility, adaptability, scalability, efficiency, interoperability and personalization.

5.

HIPAA compliance elements built right in.

6.

Stay current with standards being developed.

7.

Use of standard Electronic Data Interchange (EDI) format.

8.

An offering designed with input from manufacturers, distributors, third-party logistics providers and other stakeholders to ensure all needs are met.

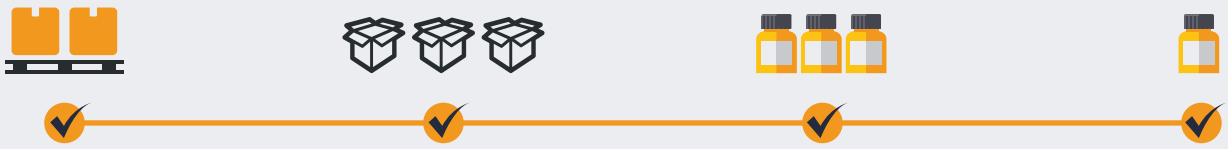
9.

DSCSA compliance as a seamless component of a warehouse management system rather than an add-on, to eliminate the need for duplicate processes.

10.

A solution that not only offers compliance now, but through 2023 as the law currently stands.

A tall order, yes. But even as challenging as compliance seems, it's not impossible.



Conclusion

Perhaps author Walter Anderson put it best: "Nothing diminishes anxiety faster than action."

Tackling the issue of DSCSA compliance will take work, sooner or later.

But addressing the issues head-on now could have big dividends in the long run. As other members of the supply chain adopt standards and move ahead, they will look for like-minded partners. Those who stay still will miss out. In addition, once the added visibility is in place, currently cumbersome processes such as expiration date tracking and recalls will be decidedly easier to handle. Those benefits can mean overall industry improvements—but also competitive advantage in the meantime.

At some point in the future, DSCSA compliance will be part of everyday operations. The sooner those days arrive, the better off all will be.

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