

Statement by

**The Healthcare Distribution Alliance (HDA)
Before the Food and Drug Administration On
“Progress Toward Implementing the Product Identification Requirements of
the Drug Supply Chain Security Act; Public Meeting;
Request for Comments”**

Docket No. FDA-2016-N-2673 [81 Fed. Reg. 64175 (September 19, 2016)]

October 14, 2016

Good morning/afternoon. I am Anita Ducca, Senior Vice President, Regulatory Affairs. With me is Brian Waldman, Partner, Arent Fox. Brian is HDA’s Outside Counsel. Thank you for the opportunity to comment on wholesale distributors’ experience implementing and planning for future implementation of the DSCSA.¹

We represent the Healthcare Distribution Alliance (HDA – formerly known as the Healthcare Distribution Management Association) and HDA’s members. HDA represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies ensure that over 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide.

In the next few minutes, I will start by addressing how it’s going and what is occupying wholesale distributors right now. During the remainder of our time, Brian will address what we

¹ The Drug Supply Chain Security Act, or DSCSA, is Title II of Public Law 113-54 and signed into effect on November 27, 2013.

believe 2023 enhanced traceability looks like and the importance of the product identifier to that new model.

You've asked for an assessment of how implementation is going and where we need further guidance.² We think Phase I of the DSCSA has been going pretty well. HDA's primary distributor members are all providing and receiving transaction data as required under the DSCSA. The biggest challenges so far for wholesale distributors have been integrating those data requirements into systems and processes and establishing the necessary connections between suppliers and customers.

Before addressing the product identifier and unit level electronic tracing, we wanted to raise an issue that has, unexpectedly and unfortunately, been diverting scarce resources away from getting ready for 2019 and 2023 requirements – and that's the lack of federal licensure regulations. Without the federal regulations, we're seeing state inspectors and state boards developing different interpretations and requirements that are inconsistent with the DSCSA and with each other. And once the federal regulations do issue, states will have to go back and amend what they've just changed, creating additional stresses for the states' limited resources, as well.

These differences and inconsistencies are unnecessarily complicating wholesale distributors' ability to obtain appropriate state licenses and are potentially opening gaps in requirements that may leave products at risk, all of which the DSCSA's national uniformity and other provisions were supposed to stop. Your help, by issuing the state licensure regulations, would be greatly appreciated.

Turning now to what's next, for wholesale distributors, significant efforts are being made to plan for the 2019 requirement to verify the product identifier before reselling a product that has

² 81 Fed. Reg. at 64176 col.3.

been returned from a customer. Given that wholesale distributors receive approximately 60 million units of saleable returns per year, this verification requirement has the potential to be very burdensome for both manufacturers and wholesalers. HDA has sponsored a pilot study with its manufacturer and wholesale distributor members to test different verification methods and we're pleased to report that our collective interpretation and implementation of the DSCSA's verification requirement did work.

We are currently moving closer to completing the analysis and review of the data and information generated during the pilots and look forward to presenting more on this extensive effort at HDA's Traceability Seminar on November 9-11 and in written comments to the Agency. One cautionary note we do want to emphasize -- the effort to set up the different verification systems that manufacturers and distributors piloted was far more complex and time consuming than anticipated, even though there was a very small number of products and trading partners involved in the pilot when compared to the "real world" volume we handle. We particularly note this experience because we believe it suggests that achieving 2023 electronic interoperability is very complex, with many unknowns, and it's going to take even longer than expected to achieve.

To that end, we want to describe our interpretation of 2023 enhanced traceability. Section 582(g) sets out the requirement of an interoperable, electronic system for the tracing of product at the package level. It builds on what is already in place under the DSCSA, including requirements that trading partners (1) be authorized (licensed or registered), (2) exchange transaction data, (3) maintain that data for six years, and (4) have systems and processes for recalls and suspect and illegitimate product investigations, and for making notifications when required.

Further, unless excepted or grandfathered, beginning November 27, 2017, manufacturers must affix or imprint a unique product identifier to each drug package and homogenous case that

the manufacturer intends to introduce in a transaction into commerce. This serialization requirement applies to repackagers on Nov. 27, 2018.

The 2023 enhanced traceability system in Section 582(g) of the Act then takes all this much further. Let me highlight 5 enhancements:

1. First, starting in 2023, the product identifier must be included in the TI³ for every transaction.
2. Second, in every product transaction, authorized trading partners must provide and receive TI and TS in a secure, interoperable, electronic manner. Each authorized trading partner must provide TI and TS to its customer, who, in turn, will provide its own TI and TS to its subsequent customer, in each case with the TI reflecting the current ownership and sale. Note that I mentioned the TI and TS, but not the third T – TH. The statute provides that the requirement to pass the Transaction History sunsets in 2023 and is no longer required.
3. Third, when appropriate, it will be possible for each trading partner to manually or electronically read the unique product identifier, and relate that identifier to the TI for that product. This means a trading partner will be able to identify, by unique product identifier, information about the transaction in which it acquired the product, and the date of that transaction. If the purchasing trading partner sells the product, it also will be able to identify, by unique product identifier, when it sold the specific unit of product, and to whom.
4. Fourth, each trading partner must have systems and processes to be able to promptly respond with the TI and TS for a product when FDA or other officials request it in the event of a recall or during suspect and illegitimate product investigations.

³ The Transaction History (TI), Transaction Information (TI) and Transaction Statement (TS) are defined in the DSCSA under Sections 581(25), (26) and (27).

5. Fifth, and last, each trading partner must have systems and processes necessary to facilitate gathering the information necessary to produce TI going back to the manufacturer in response to certain requests. These requests can arise in two situations: in recalls and in suspect and illegitimate product investigations. This doesn't mean a trading partner must produce TI going back to the manufacturer – that's the statutory definition of TH, which sunsets in 2023. Section 582(g) says that a trading partner has to facilitate gathering the TI that will enable the entity it is facilitating – likely FDA or maybe a trading partner – to assemble the TI for each transaction going back to the manufacturer.

Our focus today won't include a full exploration of the systems, processes and other mechanisms that we envision will be needed to meet the DSCSA's ultimate goals for 2023. However, we do want to point out that HDA believes that inference will be essential to accomplishing them. Inference in this context is a business process in which a collection of individual products moves through the supply chain in an outer container such as a pallet or case, and less than 100 percent of product identifiers affixed to the individual units within that outer container are scanned and/or read.

For a wholesale distributor to infer the contents of sealed cases or other containers that they purchase from manufacturers, manufacturers will have to provide wholesale distributors with data that creates the unit to case relationship of product and serialized data – referred to as “aggregation.” Moreover, manufacturers will not be alone in this, as wholesale distributors will also need to aggregate many of the shipments for their customers. Given that approximately 15 million products move to and from wholesale distributors each day, inference will be essential to allow wholesale distributors to move this volume of products. HDA strongly urges FDA to consider the need for inference and by default, aggregation.

“Facilitate gathering,” a concept mentioned earlier, also merits additional exploration as it is another, and new, requirement designed to further secure the supply chain. Trading partners have always cooperated with one another and the Agency on recalls and investigative efforts, but the DSCSA now expressly requires them to provide even greater assistance to FDA (or other appropriate entity) in such investigations.

With the application of the unique identifier on all products transacted, trading partners gain both visibility into the identity of each individual unit and the ability to trace that unit. Distributors will be able to scan or otherwise “look up” a product’s identifier and be able to give FDA or other regulatory authority exact information about the previous owner or subsequent purchaser for any product that they transacted. These identification and traceability capabilities to facilitate gathering a product’s TI are achievable because of the product serialization made possible in the DSCSA.

Moreover, a complete profile of the products’ ownership will be rapidly available because the vast majority of wholesale distributor purchases are direct purchase transactions. This means that only three entities would typically have a unit of product’s TI – the manufacturer (or the manufacturer’s exclusive distributor), the wholesale distributor and the dispenser.

We fully anticipate that the multiple additional security provisions that will have been put into place before 2023 will make instances where investigations into suspect or illegitimate products in the U.S. supply chain are very rare events. However, the additional trading partner capability that the DSCSA adds will clearly provide an important level of support for such investigations moving forward.

Uniquely identified, serialized product changing ownership in an electronic, interoperable system is also critically important to the verification the DSCSA also requires. Verification means determining whether the product identifier affixed to, or imprinted on a package or homogeneous case corresponds to the SNI that the manufacturer or repackager assigned to the product. In the DSCSA

there are two instances in which trading partners must verify that a product's identifier corresponds to the manufacturer or repackager's SNI: (1) suspect product investigations and; (2) when a wholesale distributor wants to resell a customer return. We emphasize that these are the only instances when wholesale distributors must verify a product's identifier.

Let's not forget where we were only a few years ago. The enhanced traceability for 2023 that we've described far exceeds what was required before the DSCSA was signed, and even what the DSCSA requires before 2023. In 2023, trading partners will have the ability to obtain critical transaction data about each unit of product purchased and sold based upon manually reading or electronically scanning each unit's unique identifier. Data will be shared in an electronic and interoperable format. Only three years ago, trading partners were relying upon paper pedigrees for a limited number of transactions that were non-direct purchases. Product identifiers were not incorporated into product packaging, units were not individually serialized (especially not with a unique serial number assigned by the manufacturer) and the paper pedigree could not reliably be associated with a single, specific unit. The advances of the 2023 enhanced traceability model should not be lost in the many details to move the industry to this new level of accountability. It should be recognized for what it is -- a very significant enhancement in supply chain security that is far beyond where we were only a few years ago.

That concludes our statement today. Again, thank you for this opportunity to present on the DSCSA and 2023 enhanced traceability. We're glad to take any questions.