

**Statement by the
Healthcare Distribution Alliance (HDA)
before the Food and Drug Administration
FDA DSCSA Public Meeting
Nov. 16, 2021**

Good morning. My name is Anita Ducca, Senior Vice President for Regulatory Affairs with the Healthcare Distribution Alliance (HDA). We represent primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 dispensers nationwide.

Today, I’m pleased to discuss “Enhanced Drug Distribution Security.” Long before the DSCSA’s enactment in 2013, we recognized the need to strengthen supply chain regulations, add uniformity, increase safety, bolster distributor licensure standards, and improve the identification of suspect and illegitimate products. We brought our concerns to Congress and actively participated in multi-year legislative negotiations that evolved into the DSCSA.

Since enactment, we have continued our leadership role and undertaken enormous implementation efforts. Working with other stakeholders, we developed guidances, provided numerous educational offerings, and sponsored important initiatives around bar codes, electronic data exchange, exceptions handling, verification and more.

I’ll now turn to the Agency’s Enhanced Drug Distribution Security Draft Guidance (or “EDDS Draft Guidance”) intended to facilitate 2023 implementation, only two years away, and explain our significant misgivings.

We are concerned that the EDDS Draft Guidance, rather than facilitating implementation efforts, may actually hinder them. I and some of the other speakers today will address how inconsistencies between the Draft Guidance and the industry's well-described compliance efforts will impede our shared goal of meeting the 2023 deadlines. Stepping back from the Draft Guidance's specifics, I cannot overstate the importance of achieving alignment between FDA's articulation and what industry has collectively been building over the last eight years to meet the 2023 requirements.

This is because, while FDA issues the guidances, individual state regulatory authorities inspect wholesale distributors for compliance and license them. State regulators look to FDA's guidances for interpretations of the DSCSA's requirements.

Thus, we anticipate that many states will rely on the Draft Guidance and expect that wholesale distributors will implement it as written. They often follow FDA guidances in this way, even though a guidance states it is "draft," or contains only "recommendations" or is "non-binding."

As others will also explain today, many of the compliance systems and processes they have been building, in good faith and transparently, are very different from what FDA appears to contemplate in the Draft Guidance. Many functionalities the Draft Guidance seems to expect are inconsistent with the statute and are not technologically or operationally feasible by 2023.

At best, wholesale distributors may have to spend considerable time and effort explaining to regulatory authorities why their processes comply with the statute. At worst, wholesale distributors may be extremely vulnerable to non-compliance findings and enforcement actions if regulators believe the distributors should have implemented the Draft Guidance exactly.

Moreover, the statute's complexity, coupled with Draft Guidance "recommendations" not aligned with the statute or what industry has been building, can lead to other problems, such as varying interpretations across states. We may find ourselves back to 50 different sets of state expectations. This patchwork is in total contravention to the original intent of the DSCSA –a uniform, national framework to enable DSCSA-covered drug product tracing and help protect the domestic supply chain.

I'll now turn to a few specific concerns about the Draft Guidance. As the distributors also speaking today will describe, we found certain elements of the Draft Guidance to be particularly troubling, such as the statements that

"Trading Partners... should be able to collect the relevant transaction information and transaction statement... in a rapid, electronic manner from all Trading Partners that were involved... for a product being investigated" and
[Draft Guidance at 435-437]

"FDA would expect that Federal or State officials would be able to initiate a single, targeted request for information... via the enhanced system."
[Draft Guidance at 438-439]

Taken literally, this language indicates that FDA expects all Trading Partners will have ready visibility into other Trading Partners' proprietary transaction data through an apparent "system-to-system" interface or that all supply chain transaction data will be available for querying from a central repository or interconnected databases. More recently, the Agency appears to expect that all Trading Partners and all regulators would be connected to one another through a "communications hub," as presented at FDA's October 5 webinar and HDA's recent Traceability Seminar.

But the DSCSA does not require these repositories, connections, or functionalities. Instead, consistent with the statute, Trading Partners are building point-to-point, business-to-business connections that will enable sending and receiving transaction data, including the product identifiers, for each product in a transaction.

The Verification Router System, or VRS, may have inspired the apparent expectation of full visibility into all product transactions with “one push of a button.” The VRS doesn’t do this and cannot be repurposed for such requests and responses, because:

- The entire supply chain would have to participate in, or subscribe to, such a system for it to work as envisioned. However, only a limited number of manufacturers and wholesalers, and even fewer dispensers, currently participate.
- Also, the VRS is able to direct a query about a product identifier from one Trading Partner at a time to that product’s manufacturer and provides a very limited automated response back about the product identifier – “YES” – the product identifier matches one the manufacturer assigned, or – “NO” – the product identifier does not match one the manufacturer assigned.
- The VRS can enable a few very limited additional messages, such as whether a product with that identifier is the subject of a recall. But that’s all. The VRS cannot broadcast a tracing request to all supply chain members and cannot return a complete collection of transaction data back.

The system FDA appears to envision would seemingly involve a single query going to multiple, interconnected data repositories and retrieving a tremendous volume of data. This is far different from, and enormously more complex than, the VRS system, which by the way, has taken about 5 years to develop.

A “communications hub” poses other significant hurdles as we understand the intention. For example, we believe a single entity would have to build and operate this hub and a requirement that every supply chain partner participate in it. But this communications hub is not statutorily required, doesn’t exist, isn’t being built, and cannot be built and operationalized by 2023.

Even if an entity purports to have such a system, we see enormous antitrust risks if every trading partner was expected to participate. Therefore, HDA could not support industry-wide adoption of a single, proprietary offering.

HDA described many additional concerns about the Draft Guidance in our written comments to the docket, and we intend to follow up this meeting with supplemental comments. I'll close with a few recommendations regarding the EDDS Draft Guidance:

First, we respectfully request that the Agency withdraw the Draft Guidance. Otherwise, states may begin compliance activities based on it, even though it's still in draft. Moreover, it is generating uncertainty across the supply chain that is distracting from what we need to be doing, that is, focusing on building connections between Trading Partners for interoperable transaction data exchange. Without data exchange, there will be nothing to trace in 2023.

Second, in any rewrite, we recommend focusing on what is specifically necessary for compliance. That means including only the elements required for 2023 and leaving out those not statutorily-required. Exchanging the Transaction Information (including the Product identifier) and the Transaction Statement, and a Trading Partner's ability to respond to appropriate tracing requests with the transaction data in its possession comprise key 2023 requirements.

Third, we urge the Agency to expressly state that what the industry is currently doing is "interoperable" and that industry's overall preparations as communicated to the Agency are "compliant." By endorsing these efforts, FDA will signal to inspectors and regulatory authorities that we're on the right track. This clarity is also important because, as indicated by certain remarks we recently heard, some Trading Partners saw the "communications hub" in FDA's presentations and think there's something else coming. They're deciding to wait to commit to EPCIS – which is critical for both

data exchange and tracing. But there isn't anything else. Currently, there's no other technology or solution except transaction data exchange using EPCIS standards. FDA's support for the supply chain's direction would provide the "go ahead" that some Trading Partners are waiting for.

HDA urges FDA to adopt our recommendations to help ensure patients' continued access to medicines and to support productive interactions between the supply chain and all regulatory authorities.

Thank you for this opportunity to speak.