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On Behalf of the
Healthcare Distribution Alliance (HDA)
before the Food and Drug Administration (FDA)
for the DSCSA Public Meeting[1]
Implementation and Readiness Efforts for 2023
Dec. 7 & 8, 2022

Good morning. My name is Anita Ducca, Senior Vice President for Regulatory Affairs with the Healthcare Distribution Alliance (HDA). HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 180,000 dispensers nationwide.

I'll start by thanking FDA for two important releases – first, the revised Draft Guidance on Standards for the Interoperable Exchange of Information where FDA recommended trading partners use EPCIS[2] for DSCSA transactions. We strongly support this endorsement of EPCIS. Second, we appreciated seeing the proposed rule on National Standards for the Licensure of Wholesale Drug Distributors and 3PLs.[3] While our comment's length might suggest profound disagreement, that is not the case. We support much of the rule and look forward to working with FDA on its finalization.

Turning to 2023 readiness, HDA conducted two surveys last June to gauge where manufacturers and wholesalers are on the path to next November. These surveys showed that while there has been much progress, the percentage of manufacturers who have waited until 2023 to onboard is concerning.

HDA members speaking today will address their own preparations, so I will focus my time on four areas where we see opportunities for FDA leadership, including (1) publicizing the importance of the

[1] The meeting announcement is available at: 87 Fed. Reg. 67047 (November 7, 2022). See also FDA's Meeting Webpage.
[2] EPCIS (Electronic Product Code Information Services) is a standard developed by GS1. For more information see https://www.gs1.org/standards/epcis.
[3] 87 Fed. Reg 6708 (Feb. 4, 2022).

November 27, 2023 deadline, (2) completing certain Draft Guidances, (3) providing additional guidance for State regulatory authorities and (4) greater outreach to, and clarity for, dispensers.

First, we urge FDA to continue to press trading partners on the upcoming statutory deadline. As our surveys and members will report, industry has a lot more to do. Manufacturers and wholesale distributors must establish business-to-business connections to enable the interoperable electronic provision of TI. Once the connection is established, following the EPCIS standard, manufacturers and repackagers must then provide TI with product identifiers for each product in a transaction. Without both the business-to-business connection ***and*** data exchange, there won't be compliance with 2023 interoperable data exchange requirements and FDA and other regulators won't receive an answer to a tracing request.

So, manufacturers need to onboard with their wholesale distributors, and manufacturers that do have the connections need to start sending EPCIS files with product identifiers for DSCSA-covered products. And, the sooner the better.

Given the DSCSA's interoperable, interdependent framework, compliance depends on all trading partners' collective actions. Wholesale distributors have been reaching out to manufacturers and setting up the connections. However, they can only control their own operations. If a supplier can't send TI with product identifiers in an EPCIS file, a wholesale distributor is at risk and needed medicines may not reach patients, the primary concern for all stakeholders.

Second, we urge the agency to withdraw or revise and finalize key guidances. I've already mentioned the Standards for the Interoperable Exchange of Information Draft Guidance which we recommend finalizing as soon as possible. Many of those commenting, including HDA, asked that the agency also expressly acknowledge the use of portals as being compliant for the provision, receipt and maintenance of TI. Portals are a critical way that dispensers who aren't able to establish business-to-business EPCIS connections with their suppliers will comply with the DSCSA.

Separately, HDA and others raised numerous concerns with the 2021 Enhanced Drug Distribution Security Draft Guidance (or "EDDS"). For example, this guidance did not seem to recognize that a trading partner will be responding to a regulator's tracing request by providing only the TI it has in its possession. We are very concerned that regulators, particularly State authorities, will expect that all of a product's ownership changes will be available with a single tracing request to one trading partner. So, we urge the Agency to revamp or withdraw the EDDS Draft Guidance as soon as possible.

This potential for regulator confusion brings me to my third point about where FDA leadership would be especially helpful. We believe States need greater clarity and guidance, particularly around what the DSCSA requires for compliance. For example, while FDA emphasizes that Draft Guidances are not legally binding, we hear that State regulators often expect trading partners to implement a Draft Guidance exactly. Among our concerns is that State regulators may expect that trading partners will access a "communications hub" and have "one-stop" tracing capability that the EDDS Draft Guidance seems to describe.

We also noticed that State regulators' comments regarding the proposed licensure rule indicate considerable confusion about what the States' roles will be in licensure, inspection, and enforcement. Many States disagree with FDA, or are confused, over the scope of the State laws that the DSCSA preempts. And, we emphasize, these disagreements and misunderstandings over preemption encompass both licensure requirements ***and*** tracing requirements.

The DSCSA was intended to increase supply chain security by eliminating the 50-state patchwork of varying requirements and create uniform national standards for both licensure ***and*** product tracing. While trading partners have been working for nine years to meet the law's requirements, the uniformity Congress mandated remains unrealized. States need to know which of their product tracing requirements are preempted because they are different from the DSCSA. Continuing to allow different requirements and interpretations may impede achieving interoperability.

We believe FDA guidance on how to make appropriate tracing and verification requests and what a State regulator can expect in response to such requests would also be very useful.

For my fourth and final recommendation, we encourage more outreach to the dispenser community. HDA has worked with pharmacy stakeholders, including NACDS, NCPA, APHA, and others to provide educational resources, but uncertainty about DSCSA compliance obligations persists in the dispenser community. So, we see providing greater clarity in this regard as another critical area where FDA leadership would be very helpful.

There is, in short, a great deal FDA can do to help.

I'll close by emphasizing that with much more that needs to be done to reach 2023 compliance, our members are working as hard and as fast as they can. HDA looks forward to working on implementation and continued communication with FDA over the next year.

Thank you for this opportunity to speak today.