Good morning. I am Anita Ducca, Senior Vice President, Regulatory Affairs speaking on behalf of the Healthcare Distribution Alliance (HDA) and HDA’s members. Thank you for the opportunity to comment during the first of FDA’s three meetings on Enhanced Drug Distribution Security under the Drug Supply Chain Security Act.

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.

As you discuss the 2023 requirements at your tables today, I’d like to offer HDA’s perspectives on a key part of them. The DSCSA states that a trading partner must “facilitate gathering the information necessary to produce the Transaction Information (TI) for each transaction going back to the manufacturer.”¹ We believe the plainest, and best, reading of that requirement is that the trading partner is tasked with aiding and making it easier for the primary actor – meaning FDA or other appropriate official in a recall or suspect or illegitimate product investigation – to

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¹ §582(g)(1)(E)
The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—

“(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or “

(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).
assemble the TI back to the manufacturer. This means that the trading partner must provide the TI it received for that package and, if sold to a non-patient, the TI for that sale. We do not believe the DSCSA can be read as requiring a trading partner to provide any other data for any other transaction.

Specifically, a trading partner satisfies this DSCSA requirement if it provides the TI for these two transactions. We do not interpret the DSCSA as requiring that a trading partner provide and maintain a package’s Transaction History (TH) for every transaction going back to the manufacturer, or that the data reside in one place. Congress intentionally and specifically deleted TH from end-state traceability for 2023. For that reason, we believe that the DSCSA’s 2023 requirements for “interoperable electronic tracing” of a package in a “secure, interoperable, electronic manner” means seamless interoperability between trading partners. Given that Congress expressly eliminated TH, we do not believe the DSCSA can be read as requiring end-to-end visibility from any single place in the supply chain, from point of manufacture to point of dispensing.

Also, had Congress intended to require a system with the capability, in a single query, to see a package’s entire TH, it had a model in California’s law, SB 1307. SB 1307 explicitly stated that a pedigree for a single drug package had to contain information on all previous transactions going all the way back through the supply chain, to the manufacturer’s first sale. That’s not what the DSCSA says or does. There are other reasons for this perspective, including very significant technological, security and data management constraints that effectively make such a “scan and see” system impossible. But rather than taking your time now, I’ll refer you to the detailed analysis we previously submitted to FDA’s docket.

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2 § 582(k)(1).
3 § 582(g)(1).
4 Docket No. FDA-2016-N-2673.
Let me add that we have no objection if individual companies, or business partners, on their own, wish to expand the systems they build for the DSCSA to do more than what’s required, but we feel it’s inappropriate to attempt to define them into today’s conversation. At least some will likely not be possible until the DSCSA’s specific requirements are met and we’ve already had several instances where enforcement discretion had to be used to extend deadlines for the DSCSA’s requirements, even without any “add-ons”.

There is much to talk about today as we consider other DSCSA 2023 requirements, but HDA specifically needs to raise the importance of inference and aggregation to building a functioning, interoperable system. Inference in this context is a business process in which a collection of individual products move 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. HDA believes that while inference is not specified in the DSCSA, compliance with the 2023 requirements will not be possible without it.

For a wholesale distributor to infer the contents of sealed cases or other containers, manufacturers will have to provide data that creates the unit to case relationship (aggregation) of product and serialized data. Moreover, manufacturers will not be alone in this, as wholesale distributors will also need to aggregate many of the shipments for their customers. With 15 million products moving to and from wholesale distributors each day, inference will be essential to allow wholesale distributors to move this volume efficiently.

I’m looking forward to some lively discussions at our tables today and thank you for the opportunity to speak.