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RE: Proposed Pilot Project(s) Under the Drug Supply Chain Security Act – Public Workshop; Request for Comments, 81 Fed. Reg. 7807 (Feb. 16, 2016), Dkt. No. FDA-2016-N-0407; Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information, 81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114

Dear Dr. Bernstein, Dr. Jung, and Mr. Bellingham:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) Proposed Pilot Project(s) Under the Drug Supply Chain Security Act (DSCSA); Public Workshop; Request for Comments, 81 Fed. Reg. 7807 (Feb. 16, 2016). Also, since the public workshops on April 5 and 6, FDA published an additional notice, seeking comment on Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information, 81 Fed. Reg. 22279 (April 15, 2016). We submit the attached comments to both dockets.

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA 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. HDMA and its members work daily to provide value and achieve cost

savings, an estimated \$42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

In our comments, we address the following key points, among others:

- HDMA emphasizes the importance of FDA articulating and coming to consensus with stakeholders on DSCSA terms and trading partner responsibilities in order to build pilots based upon a common understanding of the statute's requirements;
- HDMA believes there is an urgent need to clearly define the scope of any pilots and avoid "scope creep," with focused, well-managed pilots designed to yield useful, practical, actionable information;
- HDMA recommends focusing any FDA-supported pilots upon 2023 compliance and commitments, without venturing into testing what the DSCSA does not require;
- We discuss the insights we hope the HDMA Serialized Returns Pilot might be able to provide to the supply chain, recognizing that it is unknown at this initial stage, whether our Pilot of 2019 returns verification process requirements will provide significant learnings that are broad enough to inform 2023 requirements;
- HDMA encourages FDA to affirm or provide guidance concerning certain DSCSA supply chain issues, such as grandfathering, use of a serialized Global Trade Item Number (SGTIN) in the product identifier, exceptions processes, use of the Global Location Number (GLN), and use of master data; and,
- HDMA offers comments on some of the specific issues FDA identified in slides that summarized the breakout and table discussions, such as the product identifier, bar code quality, interoperability, aggregation, inference, and verification.

Of particular importance, we urge tailoring any FDA-sponsored pilots narrowly and not seek to impose what the DSCSA does not require.

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HDMA thanks you for this opportunity to provide our perspective on points raised at the recent Workshop. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs

**Comments of the Healthcare Distribution Management Association
Proposed Pilot Project(s) Under the Drug Supply Chain Security Act;
Public Workshop; Request for Comments,
81 Fed. Reg. 7807 (Feb. 16, 2016), Dkt. No. FDA-2016-N-0407
Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information
81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114
April 21, 2016**

The Healthcare Distribution Management Association (HDMA) thanks the Food and Drug Administration (FDA) for the opportunity to participate in the public Workshop on proposed pilot projects under the Drug Supply Chain Security Act (DSCSA) and now this subsequent opportunity to submit additional comments. We separate our comments into two sections: (1) a discussion of general issues and observations regarding the conduct of FDA-supported pilots under the DSCSA; and (2) certain specific issues FDA identified in slides that summarized the breakout and table discussions.

1. General Issues and Observations

a. A common understanding of the DSCSA's statutory requirements is necessary before any pilot is developed.

HDMA believes that FDA-supported pilots cannot begin unless based first upon a clear articulation of the DSCSA's requirements in 2023. The 2023 requirements are not a surprise or unknown as the DSCSA provides ten years to refine and implement them. They include:

- For each DSCSA-covered transaction, the passing and receipt of transaction information (TI) and transaction statement (TS) data (but not transaction history (TH)) between authorized trading partners in a secure, interoperable, electronic manner;
- Serialization of individual saleable units with unique product identifiers;
- Inclusion of the product identifier (which includes a standardized numerical identifier (SNI), lot number and expiration date) in the TI for each product transaction;
- In certain specified circumstances (*i.e.*, saleable returns processing by wholesale distributors; suspect or illegitimate product investigations), the systems and processes to verify that the identifier affixed to a product was one assigned by the manufacturer or repackager;
- Systems and processes that allow trading partners to promptly respond with TI and TS for a product upon request by FDA or other state or federal officials in the event of a recall or suspect or illegitimate product investigation;
- Systems and processes to promptly facilitate gathering information necessary to produce TI for a product going back to the manufacturer in the event of a request by FDA or other appropriate officials on account of a recall or suspect or illegitimate product investigation; and

- Systems and processes to promptly facilitate gathering information necessary to produce TI for a product going back to the manufacturer in the event of a request by an authorized trading partner, in a secure manner that protects confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting FDA or other appropriate official with a recall or suspect or illegitimate product investigation.

HDMA believes it will be impossible to develop pilots testing an electronic, interoperable system for the tracking of pharmaceuticals without first articulating the statutory requirements that must be met by November 27, 2023. FDA helpfully began this process at the Workshop by introducing common terms of reference important to the DSCSA and 2023 compliance, including “aggregation,” “inference,” and “interoperability.”

We appreciate the preparation and public release of these and other terms and urge the agency to similarly publish additional, important DSCSA terms and seek comment upon them. HDMA plans to review those released to date, and, if we believe further comment would be beneficial, will provide our views under the April 15 Request for Information. We believe FDA should also, through public comment, identify the responsibilities of each member of the supply chain as of November 27, 2023. In this way, FDA and stakeholders can come to consensus on DSCSA terms, requirements, and trading partner responsibilities and build pilots based upon this common understanding.

Without clear statements from FDA of what must be done and what key terms mean, much of FDA’s time, and that of pilot participants, will be consumed with determining (and possibly disputing) “who has to do what” and what the DSCSA requirements mean, rather than on actually developing the pilots. Without this essential groundwork, it will not be possible to develop useful pilots that will instruct on methods to establish a secure, interoperable, electronic system. Failing to reach agreement on a common understanding of the DSCSA would also contribute to another potential pitfall – what HDMA refers to as “scope creep” – discussed in further detail below.

b. The “scope creep” of any proposed pilot must be curtailed.

The DSCSA has already proven more difficult to implement than expected, requiring more time, longer transitions, and greater-than-anticipated resources. Achieving an electronic, interoperable system for the tracking of pharmaceuticals by 2023 will be very challenging. Given the uncertainties of what we know we *must* accomplish by November 27, 2023, this long, careful process will undoubtedly be hindered if FDA’s pilot development includes what *might* have been in the DSCSA or what *could* be achieved in some future state.

Throughout the Workshop, assumptions about the DSCSA were frequently asserted that are not in the law itself. For example, verification was often described in

very broad terms though the DSCSA is very specific about what verification is and when it must be performed. For a return from a customer to be saleable, a wholesale distributor must verify that the product identifier, including the SNI, on the product corresponds to the SNI (or lot and expiry) that the manufacturer or repackager assigned to the product. Product verification is also part of suspect product investigations.

Despite what was often assumed at the Workshop, the DSCSA *does not require* dispensers to verify product identifiers with manufacturers or repackagers at the time they dispense. Further, the DSCSA *does not require* wholesale distributors to verify product identifiers with manufacturers when they receive or sell product (other than with saleable returns).

It appeared that some Workshop attendees made similar broad assumptions about an interoperable system being one in which it is possible to scan (or otherwise read or “look up”) a product identifier and immediately see and access every previous transaction for that product, from when the manufacturer affixed the product identifier, forward. Frequently couched as intended to “facilitate gathering the information” and using the product identifier to “enhance” traceability, these hopes ignore the explicit mandate of the DSCSA – the requirement to pass TH sunsets on November 27, 2023.

The DSCSA *does not* create or contemplate an “electronic pedigree” such as that in the prior California electronic pedigree law that required a record in electronic form containing information regarding each transaction resulting in a change of ownership of a product going back to the manufacturer. The DSCSA does not contemplate or require that someone, including individual supply chain members, have the ability to trace a product all the way back to the manufacturer’s commissioning of the product identifier by simply scanning or looking up that identifier at any point in the pharmaceutical supply chain. This theoretical “electronic pedigree” is *not* the 2023 end-state set forth in the DSCSA.

HDMA states emphatically that, for now, it is imperative that FDA-supported pilots focus upon what the statute actually requires and have a direct relationship to compliance with 2023 requirements. We believe the supply chain would be ill-served by pilots that needlessly complicate what is already a lengthy, difficult, and expensive process by testing things because they would be “nice to know” or that could likely only be implemented by amending the DSCSA, such as validation on receipt or at time of dispensing, product authentication, or the creation and passing of an electronic pedigree.

We note further that, and as the Pilots Workshop demonstrated, there are widely different capabilities, knowledge, and capacity in the supply chain. In the absence of a DSCSA mandate, every member of the supply chain will not be doing the same thing, in the same way, and business processes will vary. For example, insofar as verification of product identifiers is concerned, some trading partners may elect to do more than what the DSCSA requires, or might agree to do more under a contract with a valued trading

partner. Also, even if the entity plans to do more than what the statute requires, there may be instances where it will need to use a different process, such as perform manual reading of an identifier when there are power outages during a natural disaster.

It may be useful, eventually, to attempt to design and run pilots testing theoretical systems in order to better understand if such a system is even possible in the U.S. marketplace and, if so, whether it provides any benefits over the interoperable system that will be developed under the DSCSA. If trading partners believe such extra-statutory systems and requirements are useful for their business, they may certainly sponsor and fund such pilots, voluntarily, on their own. To the extent that there are suggestions for pilots that are very narrow in their applicability, it may be that these matters are better explored as “use cases” (*i.e.*, potential test scenarios resulting in a set of event steps to achieve a particular goal) in broader pilots.

c. The HDMA Serialized Returns Pilot may provide useful insights and learnings for 2023 pilots, but is also limited.

As has been discussed, HDMA has convened a group of wholesale distributors and manufacturers to pilot test methods for verification of the product identifiers on saleable returns. Beginning November 27, 2019, a wholesale distributor must, among other things, confirm that the product identifier on the returned package corresponds to a product identifier assigned by the manufacturer (or repackager) before the distributor can resell the product. Under the DSCSA, manufacturers have 24 hours to respond to the verification request and HDMA estimates that in the U.S. pharmaceutical supply chain nearly 2 percent of all units sold in the United States are returned, resulting in over 1.1 million saleable returns a week and over 225,000 saleable returns units per day. There is the potential for the verification requirement to be an enormously burdensome process for manufacturers and wholesale distributors that could slow the distribution of vital drugs to dispensers, limit patient access to needed drugs, and increase the amount of pharmaceutical waste. The goal of the HDMA Serialized Returns Pilot (or “2019 Pilot”) is to document and quantify through pilot tests and white papers the various methods to execute product verification and determine the most efficient method or methods for achieving compliance with the DSCSA’s verification requirements effective in 2019.

At the FDA 2023 Pilots Workshop, the HDMA 2019 Pilot was referred to numerous times, with comments that the 2019 Pilot might be “leveraged” to help inform the FDA-supported 2023 pilots. Though the 2019 Pilot has not yet launched, important learnings have already emerged that we believe are potentially useful to 2023 pilot development:

- The importance of narrow, focused pilots, with clear goals;
- A well-planned pilot takes a very long time to develop;
- One pilot does not need to (and cannot) answer all questions;
- Shared understanding of key definitions and requirements is critical;

- Not all possibilities need to be piloted;
- Simpler is better;
- Participants who have participated in pilots before provide valuable insight; and
- Participants have different business needs and different capabilities.

HDMA particularly emphasizes that our experience with the 2019 Pilot development has shown that good planning for a pilot takes a long time even with concerted, sustained effort and skilled project management. FDA’s Workshop was a good beginning but much more will be needed.

Other important information might also be developed in the HDMA 2019 Pilot that could be useful in refining 2023 pilots or that identify the need for greater FDA guidance apart from a pilot, including:

- The relative efficiencies of different verification models – including the “central database,” “peer-to-peer,” and a router service to each manufacturer’s database;
- The incidence of problems with barcodes (*e.g.*, accuracy, legibility, scanability, etc.);
- The length of time it takes for one trading partner to connect with other trading partners in order to successfully exchange serialized data;
- Practices and processes that facilitated the successful exchange of serialized data between manufacturers and distributors;
- The efficiency of verification of serialized data; and
- Whether there are any barriers to adoption of certain verification methods for one or more segments of the supply chain.

Though we believe the 2019 Pilot will prove useful to the design of 2023 pilots, we emphasize its limited nature. The 2019 Pilot is testing only verification methods. Further, the 2019 Pilot is testing only one situation where verification is required – the process involving verification of saleable returns; the HDMA 2019 Pilot is not testing recalls, suspect or illegitimate product investigations, or notifications to trading partners or FDA. The only communications are between manufacturers and distributors about product identifiers and dispensers are not involved at this time. The HDMA 2019 Pilot also is not testing exceptions processes if the identifier on a product fails – that is, if it is not matched to the data from the manufacturer or is not readable.

Thus, while we are hopeful that the 2019 Pilot will yield information that may inform development of pilots to test methods to meet the DSCSA’s 2023 requirements, HDMA is taking care to accurately characterize the Pilot’s potential usage for that purpose. It is possible that some aspects of the 2019 Pilot might be scalable to the secure, interoperable, electronic system that must ultimately arise for 2023 and beyond. Until we

see the results, it is unknown whether the 2019 Pilot will provide learnings of such significant and broad applicability that they could direct (or even inform) how to comply with 2023 requirements.

d. FDA should carefully consider how pilots can be designed and managed to yield useful, practical, actionable information.

In addition to the potential for “scope creep” and the learnings from HDMA’s 2019 Pilot thus far, we offer additional suggestions for successful pilots. We believe that modest pilots with well-defined scope and goals are more likely to yield useful information. Overly complicated pilots testing highly theoretical and idiosyncratic scenarios will be difficult to manage and unlikely to provide useful insights and information with broad applicability.

Further, given the many broad and disparate ideas put forth at FDA’s Workshop, we urge resisting both the temptation to pilot every possible scenario and the expectation that a single pilot will result in a single system that will answer all DSCSA needs. We have observed an inclination to push boundaries further and further in the hope that a pilot could address, for example, not just product identifier verification, but also notifications, investigations, and recalls. There is also a proliferation of ever-more-unlikely scenarios for the entry of illegitimate product into the U.S. market – and then a scramble to try to design a pilot that could protect against these highly improbable scenarios.

HDMA believes that pilots will best serve supply chain security and patient safety by a realistic approach that recognizes the existing layers of DSCSA protections, *i.e.*, enhanced licensure requirements for 3PLs and wholesale distributors (that is, entities engaging in wholesale distribution by distributing a drug to a person other than a patient); transactions only between authorized trading partners; investigations of suspect product; greater controls on saleable returns; illegitimate product notifications; and exchange of transaction data. Rather than increasing the burdens upon the part of the supply chain that is working – the controlled, documented transactions between authorized trading partners – we believe scarce resources would be better expended upon either piloting ways to make the existing, secure and DSCSA-compliant supply chain more efficient, or focusing upon those places where FDA is actually observing the entry of illegitimate product into the U.S. supply chain.

e. Many elements discussed at the Workshop reflect a need for FDA guidance or FDA affirmation, not a pilot.

In determining what is and is not appropriate to pilot, HDMA also believes that certain elements and requirements have emerged where, rather than piloting, there is a need for clear FDA interpretations and guidance. This issue arose numerous times in various contexts at the Workshop; we provide some examples below.

- i. Grandfathering** We do not believe it is necessary to pilot the handling of unserialized product and product that is serialized but, prior to November 27, 2023, the product identifier is not included in TI. Focusing upon these temporary, transitory circumstances is an unnecessary distraction. Rather than wasting resources on piloting what the normal course of manufacturing, distribution, dispensing, and inventory turnover will eventually resolve, HDMA urges FDA to provide guidance on the scope and meaning of grandfathering under these circumstances. For many years, trading partners will be concurrently transacting with serialized and unserialized products, and serialized products with and without data will be moving through the supply chain simultaneously. FDA guidance would be very helpful in assuring an orderly transition.
- ii. The Global Trade Item Number (GTIN)** HDMA agrees with the views expressed at the Workshop that it is unnecessary to pilot the GTIN as an element of the product identifier. The 14-digit GTIN (Global Trade Item Number) is used by a company to uniquely identify all of its trade items. GTINs are subject to rules and standards of GS1, a global standards-setting organization. In the global pharmaceutical supply chain, there has been a gradual but significant gravitation towards use of the 14-digit GTIN as a product identifier. Many countries that have serialization requirements are using the GTIN to identify products.

Under the GS1 GTIN standards, a drug's NDC number may be embedded in the GTIN. Significantly, the DSCSA's standards for the SNI are met by a GTIN (referred to as the "serialized GTIN" or "SGTIN"). When the product's lot number and expiration date accompany the SGTIN, this three-part sequence becomes a DSCSA-compliant product identifier, in other words, SGTIN (which includes the drug's NDC number) + lot number + expiration date = DSCSA-compliant product identifier.

Rather than expressly piloting the acceptability of SGTIN-containing product identifiers, the supply chain needs FDA to revise the current Final Guidance: *Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages*. Based upon this guidance, HDMA members have observed that some manufacturers and repackagers believe they must use a product identifier based upon an NDC number plus 20 digits. FDA should align the existing SNI guidance with the DSCSA and

clearly support a serialized 14-digit GTIN plus lot number and expiration date as the product identifier.

We note that in the absence of FDA guidance on the SNI and product identifier, manufacturers have already had to begin changing packaging and manufacturing in order to meet the November 2017 product serialization deadline; some products have been serialized for many years for a manufacturer’s own internal business reasons. Regardless, to the extent FDA promulgates product identifier guidance that differs from what a manufacturer is already doing, the industry will require time to alter its practices.

- iii. **Exceptions Handling** At the Workshop, participants discussed the problems that may arise during a pilot from mismatches between data and product and other errors in transactions with well-established trading partners that are most likely due to human error and technical “glitches.” While the incidence of and reasons for such errors might be a useful finding from a pilot, including HDMA’s own 2019 Pilot, HDMA does not believe that designing pilots specifically around the processing of exceptions would be useful.

We do believe it will be necessary to refine processes around suspect product and FDA’s *Draft Guidance for Industry: Identification of Suspect Product and Notification* to assure that every initial transaction-related mismatch between established trading partners **does not** trigger a full suspect product investigation. More nuanced guidance and business processes will help the supply chain to rationally address these mismatches while still maintaining robust systems for the identification and investigation of suspicious products.

- iv. **The Global Location Number (GLN)** In both table discussions and the general reporting thereafter, Workshop participants expressed an interest in using the GLN as a means to identify a business entity. There are many different location numbers in use in the supply chain. Like the GTIN, the GLN has the advantage of being subject to rules and standards of GS1, an international standards-setting organization. The GLN is a unique number, complying with GS1 global standards, which can be used to access master data about a location of a business entity. (By “master data,” we mean a single source of common business data used across multiple systems, applications, and/or processes – in the case of the GLN the number is linked to the name and address of a particular business.)

A GLN is crucial to EPCIS, a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain. A supply chain participant must have a GLN to participate in EPCIS. Many supply chain partners are looking to EPCIS as the likely standard protocol for exchange of DSCSA transaction data. This would mean migration to the GLN as a means to identify companies.

HDMA does not believe that use of the GLN is an issue to be piloted, though further discussion is warranted and guidance from FDA around the use of a location identifier will be necessary to achieve 2023 interoperability. HDMA urges FDA to recognize the GLN as a corporate/business identifier appropriate for use in DSCSA transactions. We emphasize that this identifier would represent the owner – the buyer or seller – of a product in a transaction and not the physical location where product is sent or received. The DSCSA is concerned with changes in ownership, not possession, and use of the GLN should not confuse this critically important distinction.

Another area for FDA to address with stakeholders is that, despite the importance of the GLN to 2023 interoperability, some supply chain entities – and especially dispensers – do not have GLNs and there are costs to acquire them from GS1 and to maintain them.

- v. **Use of Master Data** HDMA does not believe master data use is appropriate for piloting at this juncture. HDMA agrees with pilot participants that using and relying upon master data could reduce the amount of redundant, static data that must be transmitted and stored by trading partners. HDMA looks forward to working with FDA and its supply chain partners on exploring the possible efficiencies of master data, while still achieving compliance with the DSCSA’s requirements.
- vi. **Special Scenarios** Several Workshop participants voiced support for pilot testing certain exceptions to normal transactions and regular products, such as 340B transactions, drop shipments, and investigational drugs. We do not believe that all supply chain partners need to be involved in testing all of these issues, nor do we believe that each will need its own, individual FDA-supported pilot. For example, since wholesale distributors do not transmit data for drop shipments, they would not need to be involved in a pilot of drop shipments. However, individual trading partners sending and receiving drop shipment products may wish to establish a pilot for

drop shipment instances. We also believe that it is unlikely that 340B – related transactions will need their own, individual, pilot. Rather, further exploration of incorporation of 340B products into other potential pilots, may be a more appropriate approach.

Further, to the extent the DSCSA is unclear on these and other similar situations, it may also be appropriate for FDA to – and in some cases already has – provide guidance to industry. An example is the recent First Responder Guidance. To the extent there is trading partner uncertainty about specific types of products and/or transactions, could be resolved when FDA announces and implements the expected guidance on the process by which stakeholders may obtain waivers, exceptions and exemptions from DSCSA requirements.

These types of special scenarios might also be explicated further in “use cases” associated within a larger pilot.

- vii. **EPCIS** As discussed above, many supply chain partners are looking to EPCIS as the standard for exchange of transaction data. EPCIS is a GS1 internationally-recognized, standard protocol, ratified by the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC), for trading partners to share information about the physical movement of products through the supply chain. EPCIS is the data exchange mechanism being used in some of the scenarios being tested in the HDMA 2019 Pilot. We believe that EPCIS does not need to be piloted separately but information in pilots where EPCIS is used will likely generate useful information.

2. Pilot Elements

Below, we discuss certain specific issues FDA identified in slides that summarized the table discussions.

a. Product Identifier

Many manufacturers have already begun to comply with 2017 serialization requirements by affixing, or planning to affix, to applicable products a 2-D datamatrix encoded with the SGTIN, lot number, and expiration date. HDMA agrees with the views expressed at the Workshop that it is unnecessary to pilot this product identifier. What is necessary is for FDA to acknowledge and clearly affirm that the SGTIN, lot number, and expiration date in a 2-D data matrix meet the DSCSA requirements for an SNI and product identifier. HDMA urges FDA to revise the Final Guidance: *Standards for*

Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages and specifically endorse the SGTIN, lot number, and expiration date as the product identifier under the DSCSA.

b. Barcode Quality

HDMA agrees with the views expressed at the Workshop that it is unnecessary to develop separate, individual pilots specifically to evaluate barcode quality. In conjunction with wholesale distributor and manufacturer members, HDMA is preparing updates to its *Bar Code Quick Start* and *Bar Code Guidelines* which help guide industry on formatting and placement of 2-dimensional barcodes. As it is in the interest of the collective supply chain for all barcodes to be readable and error-free, we believe manufacturers and repackagers will naturally gravitate to appropriate, readable formats.

c. Interoperability

From the table discussions, various ideas were offered for how to develop and pilot a secure, interoperable, electronic system for the exchange of TI and TS between trading partners and how such a system might aid suspect and illegitimate product investigations. HDMA believes that, at this early juncture, the process would be well-served by identifying the traits that would be necessary for an interoperable system. We believe a truly interoperable system would need the following attributes:

- Achieve DSCSA compliance;
- Usable;
- Highly secure;
- Accessible by only the appropriate individuals and entities;
- Allow for trading partners to continue to efficiently meet existing “just in time” delivery deadlines;
- Cost effective;
- Reliable; and
- Have standardized data formats and clearly defined data elements.

An interoperable system will also need to be used by many different types of stakeholders who range widely in capability, capacity and sophistication and who operate on very different business platforms and models. For instance, an independent pharmacy, retail chain pharmacy, hospital pharmacy, and long term care facility are all very different from one another. An interoperable electronic system will need to account for these types of differences.

At this time, we would be reluctant to rule out any particular, potentially interoperable system, including a central data repository. We recognize, however, the formidable barriers to such a system, including cost, management, data ownership, and security. We caution that the fact that HDMA is testing both a central data repository and

establishment of a router service to each manufacturer’s database as part of the HDMA 2019 Pilot does not mean that either model is appropriate for a system that can meet 2023 interoperability requirements. We do not yet know what the HDMA 2019 Pilot will demonstrate for these systems. Further, as discussed above, HDMA’s 2019 Pilot focuses only upon one DSCSA requirement and business process – verification of the product identifier in saleable returns. It is unknown if such a system, even if successful with returns verification, could be scaled up to encompass the data generated in all product transactions to satisfy 2023 requirements.

Having discussed above what HDMA believes are the attributes of a secure, interoperable, electronic system for the exchange of TI and TS between trading partners, HDMA wishes to emphasize what does not constitute “interoperable” under the DSCSA. Specifically, HDMA rejects any assumption or argument that the DSCSA’s contemplated secure, interoperable electronic system is, in fact, an electronic pedigree-type system that allows a user to scan (or otherwise read) a single identifier and obtain a product’s entire history back from point of manufacture. The DSCSA is explicit that the provisions requiring transmission of TH sunset on November 27, 2023. The DSCSA also limits when trading partners and government officials may obtain transaction data.

HDMA does not believe that interoperability may be defined in such a way as to require what the DSCSA specifically and expressly does not require. To that end, we see no benefit to pilot testing an electronic pedigree-type of system that is explicitly outside the statute. Trading partners might, on their own, explore such systems but the already complex process of DSCSA implementation should not become mired in FDA-supported pilots testing theoretical systems that are contrary to the DSCSA.

d. Aggregation and Inference

HDMA believes that aggregation and inference are critical to the success of product traceability. The entire supply chain is significantly aided by aggregation and inference and we do not believe that implementation of the DSCSA’s interoperable vision is possible without it. ***We believe aggregation and inference is so important to the entire supply chain, and so widely recognized as such, HDMA does not see the utility of any pilot that does not incorporate these processes.*** We intend to address aggregation and inference further in separate comments to be submitted to Docket No. FDA-2016-N-1114.

e. Verification

HDMA has addressed in detail above its concerns that the DSCSA’s verification requirements not become an excuse for developing systems that the statute does not require, such as continuing the requirement after November 27, 2023 to maintain and provide access to a product’s full TH. Additionally, the DSCSA’s verification processes

for suspect and illegitimate product investigations do not and cannot justify establishment of a full electronic pedigree when the DSCSA itself does not require it.

With recognition of the limited circumstances that do require verification under the DSCSA, HDMA believes that piloting processes and methods related to suspect product investigations and illegitimate product notifications might be useful for the agency. A pilot could look at how long it takes to generate TI and TS going back to the manufacturer and which methods produce the requested information via means that are fast, efficient, and accurate, but with minimal disruption to regular pharmaceutical distribution.

f. Notification

While HDMA does not object to a pilot to examine notification procedures and processes, we also do not believe that piloting this part of the DSCSA requirements would be a priority. While important, notification to FDA is already a requirement and processes and procedures should already be in place. By 2023, such procedures should have been well established.

3. Conclusion

HDMA thanks FDA for this opportunity to participate in the Pilots Workshop and to submit these comments. If you have any questions or if HDMA can provide further information that may be helpful, please do not hesitate to contact Anita Ducca, Senior Vice President, Regulatory Affairs, at 703-885-0240 or at aducca@hdmanet.org.