Healthcare Distribution Alliance Comments on Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments 81 Fed. Reg. 64175 (Sept. 19, 2016), Dkt. No. FDA-2016-N-2673

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act[1] (DSCSA), 81 Fed. Reg. 64175 (Sept. 19, 2016). HDA previously participated in the public meeting FDA convened on October 14, 2016 regarding the product identifier and other requirements of the DSCSA.

Here, in response to FDA's request for comments, we address the following ten issues:

I. The HDA vision of the 2023 interoperable, electronic system;
II. Verification requirements within the DSCSA;
III. An explanation of inference and aggregation and why both are critical to DSCSA implementation;
IV. HDA's position on the request for a delay to the requirement to verify saleable returns;
V. The need for FDA to issue federal licensure standards;
VI. The utility of clear FDA guidance on GS1 standards, product identifiers, NDC conversion and barcode formatting;
VII. The importance of distinguishing between suspect/illegitimate product and a mismatch between product and DSCSA-related data;
VIII. A summary of the Saleable Returns Pilot HDA wholesale distributor and manufacturer members have undertaken regarding verification of saleable returns;
IX. DSCSA implementation focus upon building toward a 2023 system; and,
X. The need for guidances on grandfathering and waivers, exceptions and exemptions.

We also attach an Addendum discussing the challenges presented by the conflict between U.S. and India traceability requirements.

I. HDA's Vision of a Safe, Secure, Electronic and Interoperable System for Drug Product Tracing for 2023 and Beyond

At the October 14, 2016 meeting, HDA presented its interpretation of the DSCSA's mandate for "enhanced drug distribution security" in 2023 which requires the "interoperable, electronic

[1] The DSCSA amended the Federal Food, Drug and Cosmetic Act (FDC Act) and all citations that follow refer to where a particular provision of the DSCSA resides in the FDC Act, and not as that provision was codified in the U.S. Code. As an example, the DSCSA added a new § 582 to the FDC Act, now codified at 21 U.S.C. § 360eee-1; this comment will cite to § 582 of the FDC Act and, for simplicity, will not also include the citation to 21 U.S.C. § 360eee-1.

tracing of product at the package level."[2] HDA elaborates on its understanding of the DSCSA's 2023 requirements further below.

Summary of HDA's Position: For 2023 and beyond, the DSCSA creates an enhanced interoperable, electronic system where each authorized trading partner provides transaction information [TI] and a transaction statement [TS] to its customer, but not transaction history [TH]. If the customer, in turn, sells the product, it provides its own TI and TS to its subsequent customer, in each case with the TI reflecting *only* the current ownership and sale.

Recommendation to FDA: We believe that development and implementation of a 2023 interoperable electronic system (or systems) would be vastly aided by FDA's express support for the interpretation summarized here. We ask that FDA announce that position as early as possible to give stakeholders sufficient time to adopt and implement the Agency's interpretations.

A. The Product Identifier and Achieving Full Traceability

As of November 27, 2023, the "interoperable, electronic tracing of product at the package level requirements shall go into effect."[3] Section 582(g)(1)(A)-(F) sets out the different elements of this interoperable, electronic system that includes the exchange of TI and TS between authorized trading partners, the inclusion in the TI of a product identifier at the package level for each package in the transaction, and systems and processes for verification and suspect and illegitimate product investigations and recalls.[4]

Manufacturers must begin affixing a unique product identifier[5] to each drug package and homogenous case by November 27, 2017.[6] The traceability model set out in § 582(g) for 2023 and beyond is a significant enhancement over the current state as it uses and builds upon the capabilities of the product identifier and unit-level serialization, and the passing of that identifier in TI with each transaction.

With the affixing of a unique product identifier on each package and homogenous case, § 582(g)(1) contemplates a chain of data that will link each saleable product unit to the selling and purchasing sources of the product unit in a secure, interoperable, electronic system. In this enhanced distribution model, 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

[2] § 582(g)(1).

[3] § 582(g)(1).

[4] § 582(g)(1)(A)-(F).

[5] The product identifier is a standardized graphic in human-readable form and on a machine-readable carrier that conforms to international standards and includes the product's unique standardized numerical identifier (SNI), lot number, and expiration date. § 581(14) (definition of product identifier); § 581(20) (definition of SNI).

[6] § 582(b)(2)(A).

with the TI reflecting the current ownership and sale.[7] Under § 582(g)(1), the selling trading partner provides TI and TS only for that current transaction and provides no TI to its customer regarding any prior sales – that is, the selling trading partner will not provide, and the DSCSA does not require that it provide, TH of the prior sales.[8]

B. The DSCSA Builds an Enhanced System for Drug Traceability, Not an Electronic Pedigree System

The DSCSA builds over its ten-year implementation a highly protective, secure, traceability system that significantly enhances supply chain security over the pre-2014, pre-DSCSA state. However, HDA is aware of arguments by other stakeholders that the DSCSA contemplates something else – a type of electronic "pedigree" or "scan-and-see" system where it is possible to "look up" a product identifier and immediately access every previous transaction for that product.[9] For numerous reasons, HDA does not see a basis for this scan-and-see interpretation in the DSCSA.

1. Congress Expressly and Explicitly Eliminates TH

Under § 582(k)(1), TH sunsets and drops from DSCSA requirements automatically, by operation of law, on November 27, 2023. Consistent with the sunsetting of TH requirements, the DSCSA's 2023 vision of "enhanced drug distribution security" set out in § 582(g)(1)(A)-(E) does not mention TH at all. In § 582(g)(1), only TI and TS are identified, trading partners only exchange and maintain TI and TS, and, in certain recall situations and suspect and illegitimate investigations, trading partners need only produce TI, or TI and TS.

Congress's deletion of TH from end-state traceability for 2023 should not be treated as accidental. TH appears elsewhere in the DSCSA and, during the statute's long phase-in, TH must be maintained and passed in certain transactions. However, on November 27, 2023, the requirements relating to TH "shall have no force or effect."[10] When, as in the DSCSA, "Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate

[7] § 582(g)(1)(A) (authorized trading partners exchange TI and TS, but not TH, in a secure, interoperable, electronic manner).

[8] TI "for each prior transaction going back to the manufacturer of the product" is the definition of TH. § 581(25).

[9] *See, e.g.*, April 21, 2016 Comments on Proposed Pilot Project(s) Under the Drug Supply Chain Security Act; Public Workshop; Request for Comments (Docket No. FDA-2016-N-0407) submitted by PhRMA at 2-3 (urging "systems and processes that are fully connected and truly interoperable" so that "a single query can access all available information across databases" and characterizing the system HDA describes as the "one up, one back approach." This argument that the DSCSA contemplates a full electronic pedigree or some type of "scan-and-see" system was also advanced by participants at the FDA pilots Workshop in April 2016 and by LSPediA at the October 14, 2016 public meeting.

[10] § 582(k)(1).

inclusion or exclusion."[11] Furthermore, courts (and FDA) must, wherever possible, give effect to all parts of a statute.[12] Interpreting the general phrases of § 582(g)(1) as imposing duties regarding TH that § 582(k)(1) expressly nullifies would render § 582(k)(1) meaningless and neither Congress nor the courts favor such results.

Additionally, had Congress intended to continue requiring the maintenance and passing of TH, it had a model in California's electronic pedigree law, SB 1307. SB 1307 explicitly stated that a pedigree had to contain, electronically, "information regarding each transaction" from the manufacturer, to other supply chain partners, to point of administration or dispensing to the patient and that the pedigree had to be maintained through all stages of distribution.[13]

In contrast to SB 1307, the DSCSA specifically eliminated the requirement to pass or maintain TH going back to the manufacturer's first sale and the statute contains none of the specific language in the California law that gave rise to the electronic pedigree requirements. The DSCSA preempted SB 1307 and other State pedigree laws to establish a uniform national policy for the tracing of pharmaceuticals.[14] If Congress – including the California congressional delegation that participated in crafting the DSCSA – had intended to permit a single query to access all of a product's transaction data, the template for that requirement was in SB 1307. That requisite language is not in the DSCSA.

2. "Facilitate Gathering the Information" Does Not Establish an Electronic Pedigree

The DSCSA states that in order to respond to certain requests in recall situations and suspect and illegitimate product investigations, trading partners must have "systems and processes necessary ***to promptly facilitate gathering the information necessary to produce the [TI] for each transaction going back to the manufacturer***."[15] Some argue that this phrase necessitates more than the enhanced traceability described above and that this phrase in the DSCSA requires something more akin to California's SB 1307 electronic pedigree (with all transactional data about a product, going all the way back to the manufacturer's initial sale, available in a single place and viewable with a single scan). However, by its clear and express terms, the DSCSA ***does not***

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[11] This principle and tool in interpretation of statutes, is expressio unius est exclusio alterius – the expression of one thing is the exclusion of the other. *See, e.g Am. Methyl Corp. v. E.P.A.*, 749 F.2d 826, 835–36 (D.C. Cir. 1984) (the "mention of one thing implies exclusion of another thing" is a "common sense observation … frequently invoked by the Supreme Court in construing statutes") (internal citations and footnotes omitted); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1058-59 (D.C. Cir. 1995) (statute's enumeration of one specific criterion implicitly barred agency decision based upon other factors not enumerated).

[12] *See e.g., Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973).

[13] *See* § 2 of SB 1307.

[14] § 585(b)(1).

[15] § 582(g)(1)(E) (emphasis supplied).

require a single trading partner to produce the TI for each transaction going back to the manufacturer, but only to "facilitate" locating that information. The term "facilitate" in § 582(g)(1)(E) does not suggest a duty beyond the obvious one of helping to gather the necessary information.

In the absence of a specified or technical meaning, words in statutes are attributed their ordinary meaning such as would be found in dictionaries.[16] Its "common usage … limits 'facilitate' to the efforts of someone other than the primary or necessary actor…"[17]

Thus, a trading partner that must "facilitate gathering the information necessary to produce the [TI] for each transaction going back to the manufacturer" is not the primary or necessary actor responsible for production of TI back to the manufacturer. Rather, the trading partner is tasked by the DSCSA to aid, assist and make it easier for the primary actor – likely FDA or other appropriate official – to assemble the TI back to the manufacturer.

3. <u>An Electronic Pedigree System Would Be Unduly Complex</u>

Even assuming that the general provisions of § 582(g)(1) regarding systems and processes could somehow nullify the express sunsetting of TH requirements in § 582(k)(1), there are other significant, practical hurdles to implementing an electronic pedigree back to the manufacturer or "scan-and-see" system. Most fundamentally, such a system does not currently exist. In all likelihood, implementation would involve creating a central database, or a mechanism to interconnect databases, to house data related to the millions of drug product transactions that occur every day.[18] Development and design, access, funding, data ownership, database maintenance, achieving industry-wide participation, protecting confidential commercial information, and assuring security of the data (which would be a temptingly lucrative target for counterfeiters and hackers) all pose hurdles to any centralized system.

HDA also believes that this type of electronic pedigree system would add unnecessary complexity given that the vast majority of DSCSA-covered transactions are made through members of HDA, and the vast majority of those are direct-purchase transactions.[19] Should a

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[16] *See e.g., Perrin v. United States*, 444 U.S. 37, 42 (1979) ("words will be interpreted as taking their ordinary, contemporary, common meaning"); *CSX Transp. Inc. v. Alabama Dept. of Revenue*, 131 S. Ct. 1101, 1108 (2011); *(*citing *Webster's Third New International Dictionary* for meanings of ordinary words).

[17] *Abuelhawa v. U.S.*, 129 S. Ct. 2102, 2106 (2009).

[18] The HDA Saleable Returns Pilot (*see* Section VIII) did test a central database model. However, this database was for the purpose only of verifying the product identifier of a saleable return against a database of product identifiers manufacturers provided. The tested model was far more limited than what would have to be stored in a central database to meet 2023 interoperability requirements; the piloted model did not include any other TI and TS data.

[19] *See, e.g.*, Center for Healthcare Supply Chain Research/2015-2016 HDA Factbook; Tables 1 through 4. According to Table 4 of the Factbook, only 0.2 percent of HDA members' sales are to "other distributors" and only 0.9 percent are to "other customers". (Note, in June 2016, HDA's Center for Healthcare Supply Chain Research changed its name to "The HDA Research Foundation").

wholesale distributor or dispenser receive a request from FDA or other official, or a trading partner, in a recall situation or suspect or illegitimate product investigation, the tracing of a product by its identifier should be straightforward: (1) the dispenser will be able to identify the wholesale distributor from whom it purchased the product; and (2) the wholesale distributor will be able to identify the transaction in which it acquired the product from the manufacturer.

Further, though a very complex database would likely have to be created and maintained, it would, in fact, be used rarely as the DSCSA would permit access to the TI and TS within the database only under very limited circumstances.[20]

II. Verification Under the DSCSA

In the DSCSA, verification is a very specific process that must be performed in carefully delineated circumstances. Section 581(28) defines verification as follows:

> The term 'verification' or 'verify' means determining whether the product identifier affixed to, or imprinted upon, on a package or homogeneous case corresponds to the standardized numerical identifier [SNI] … assigned to the product by the manufacturer or the repackager….[21]

At both the pilots Workshop in April 2016 and the public meeting on October 14, HDA has observed some stakeholders advancing the view that wholesale distributors should "verify" the product identifiers on drugs before sale and/or that dispensers should verify product identifiers before dispensing them. HDA believes this is an incorrect reading of the DSCSA.

Summary of HDA's Position: There are only two instances in which trading partners must verify that a product's identifier corresponds to the SNI the manufacturer or repackager assigned to the product: (1) suspect product investigations and; (2) a wholesale distributor's or manufacturer's saleable returns.

Recommendation to FDA: FDA should resist any calls to impose verification requirements upon trading partners if such requirements are not supported by the DSCSA.

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[20] Sections 582(g)(1)(D) and (E) permit access to a trading partner's transaction data only in recall situations and suspect and illegitimate product investigations. A centralized database of all product transaction data could also be used, theoretically, for verification of saleable returns, a requirement wholesale distributors must begin implementing in 2019. This centralized database model was one of nine tested in HDA's Saleable Returns Pilot, which is discussed in Section VIII.

[21] Section 581(28) also permits verification of a product identifier by "lot number and expiration date." However, once all product is serialized, HDA believes there would be no reason for trading partners to verify product by lot number and expiration date when the product identifier (which includes the SNI, lot number, and expiration date (§ 581(14)) would be more accurate and efficient.

In the DSCSA there are ***only two*** situations in which trading partners are required to verify that a product's identifier corresponds to the SNI the manufacturer or repackager assigned:

- Manufacturers, wholesale distributors, repackagers,[22] and dispensers[23] must verify product identifiers in suspect product investigations; and
- Manufacturers and wholesale distributors must verify any returned product it intends to resell (beginning November 27, 2017 for manufacturers and November 27, 2019 for wholesale distributors).[24]

Dispensers have additional requirements in suspect product investigations regarding lot number verification; they must also verify the product identifier of at least three packages or 10 percent of such suspect product (whichever is greater, or all if fewer than three).[25] Additionally, a manufacturer (or repackager) must respond to a verification request from a repackager, wholesale distributor, or dispenser within 24 hours (or such other time FDA establishes).[26] The "enhanced drug distribution" described in § 582(g)(1)(C) states that each trading partner must have "[s]ystems and processes" to conduct this verification of product at the package level.

Most significantly, ***nothing*** in the DSCSA supports creating additional, affirmative duties to verify a product's identifier beyond the limited circumstances of suspect product investigations and saleable returns. The DSCSA is painstakingly and exhaustingly clear on exactly when a wholesale distributor, manufacturer, or a dispenser must verify a product – specifying even how many products on a percentage and numerical basis a dispenser must verify in suspect product investigations,[27] how many hours a manufacturer or repackager has to respond to verification requests,[28] and that wholesale distributors and manufacturers must verify returns before reselling

[22] Upon making a determination that a product is suspect, or upon receiving a verification request FDA, manufacturers, wholesale distributors, and repackagers must be able to "promptly conduct an investigation in coordination with trading partners" to determine whether the product is an illegitimate product; the investigation shall include validating any applicable TI and TH the manufacturer, wholesale distributor, or repackager possesses and investigating whether the product is illegitimate product. § 582(b)(4)(A)(i)(II) (manufacturer); § 582(c)(4)(A)(i)(II) (wholesale distributor); § 582(e)(4)(A)(i)(II) (repackager). As the requirements for receipt and transmission of TH sunsets in 2023, there would be no TH for a trading partner to validate after November 27, 2023.

[23] A dispenser must "promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product." § 582(d)(4)(A)(i)(II)). The investigation shall include "validating any applicable" TI and TH. § 582(d)(4)(A)(ii)(III). As the requirements for receipt and transmission of TH sunsets in 2023, there would be no TH for a trading partner to validate after November 27, 2023.

[24] § 582(b)4)(E) (manufacturers) § 582(c)(4)(D) (wholesale distributors).

[25] §§ 582(d)(4)(ii)(II).

[26] § 582(b)(4)(C) (manufacturers); § 582(e)(4)(C) (repackagers).

[27] *See* § 582(d)(4)(ii)(II).

[28] § 582(b)(4)(C) (manufacturers); § 582(e)(4)(C) (repackagers).

them.[29] Given the specificity of these verification requirements, there is no rational justification for extending verification to wholesale distributor product sales that Congress did not identify in the DSCSA; similarly, there is no basis for requiring dispensers to verify a drug's product identifier upon receipt or prior to dispensing.

When, as here, Congress includes particular language in one section of a law, and omits it in another, it is presumed that the inclusion or exclusion is deliberate.[30] Simply put, the DSCSA's specific enumeration of when trading partners must verify product identifiers precludes expanding verification to other circumstances not enumerated in the statute.[31]

III. Inference and Aggregation are Crucial to an Efficient Supply Chain

In establishing an interoperable, electronic system for the tracing of products, FDA must issue guidance on the use of inference and aggregation.[32] HDA explains in this section why it believes inference and aggregation are necessary for package-level traceability.

Summary of HDA's Position: Wholesale distributors believe that inference is critical to efficient pharmaceutical distribution given both the volume of products moving through wholesale distribution centers on a daily basis and the importance of maintaining secure operations. Aggregation would be necessary to support inference in a traceability environment.

Recommendation to FDA: As discussed in our more detailed recommendations below, HDA recommends that FDA recognize and encourage through guidance the use of inference and aggregation.

A. Inference and Aggregation in the DSCSA

Under the DSCSA, each individual unit and homogenous case a manufacturer places into commerce must, beginning 2017 (and 2018 for repackagers), bear a product identifier in a standardized graphic in human-readable form and on a machine-readable carrier that conforms to international standards.[33] These are likely to be, and the industry is moving to affix and read, two dimensional (2D) data matrix barcodes.

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[29] § 582(b)4)(E) (manufacturers) § 582(c)(4)(D) (wholesale distributors).
[30] *See I.N.S.* at 432.

[31] As discussed above, this principle and tool in interpretation of statutes, is *expressio unius est exclusio alterius* – the expression of one thing is the exclusion of the other. *See, e.g.*, note 11; *Am. Methyl Corp.*, 749 F.2d at 835–36; *Ethyl Corp.*, 51 F.3d at1058-59.

[32] § 582(h)(3)(A).

[33] § 582(b)(2)(A).

In this context, **aggregation** is the collecting of units or parts into a mass or a whole. In the healthcare supply chain, this term refers to the process of creating a data hierarchy whereby the product identifiers for individual product packages ("unit level") are gathered and associated with the identifier for the larger shipping container (*e.g.*, pallets, cases, totes, etc.) for those products.

Inference means to derive a conclusion based on facts presented. The need for inference arises in the DSCSA because the 2D data matrix barcode affixed to each package utilizes "line of sight" technology and so individual units within a homogenous case cannot be read without opening the case and scanning each individual barcode. Inference applies in instances where a collection is moved through the supply chain in an outer container (*e.g.*, pallets, cases, totes, etc.), and less than 100 percent of data carriers in that collection are read by recipients.[34]

The DSCSA mandates that FDA issue guidance that:

> define[s] the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in the most efficient manner practicable, infer the contents of a case, pallet, tote, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, tote, or other aggregate, without opening each case, pallet, tote, or other aggregate or otherwise individually scanning each package…[35]

Section 582(h)(3)(A)(ii) also requires the guidance to, among other things, identify methods and processes to enhance secure product tracing, including the use of inference and aggregation.

The DSCSA's embrace of inference and aggregation are also implied in the statute's definition of "homogenous case"[36] and the fact that all homogenous cases must bear product identifiers.[37] Both are prerequisites necessary for the use of inference and aggregation. Defining "homogenous case" and requiring that it bear a product identifier enables aggregating the identifiers of the individual units in the case to the case's product identifier. In the discussion that follows we describe the form we believe the required guidance should take.

B. Inference and Aggregation are Necessary

The DSCSA enables inference and aggregation and FDA must issue guidance on its use. The need for inference and aggregation for wholesale distributors arises from the daily volume of

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[34] GS1 Healthcare. *The Practice of Inference in the U.S. Pharmaceutical Supply Chain*. (May 2010).

[35] § 582(h)(3)(A)(i).

[36] § 581(7) ("The term 'homogeneous case' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot).

[37] § 582(b)(2)(A).

business a typical distributor receives and handles. HDA member companies must receive enough products to enable them to safely and efficiently deliver, on a daily basis, 15 million prescription medicines and healthcare products to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. To meet this demand, a typical HDA member distribution center receives products constantly from hundreds or even thousands of manufacturers, often in very large case and pallet quantities, simply to meet healthcare and patient needs. Each day, a typical distribution center handles over 5,700 customer orders, and "picks" (processes) an average of over 100,000 product units.[38] Due to this high volume and the associated need to preserve efficiencies of scale, it is neither practical nor economically feasible for a wholesale distributor to scan upon receipt each individual product package that bears a "line of sight" 2D data matrix barcode.

Moreover, supply chain integrity practices advise opening sealed cases only when items are staged for picking operations. Maintaining original manufacturer-sealed cases better protects products and limits the number of open cases in warehouses or on receiving platforms, thereby creating fewer opportunities for damage and limiting the number of personnel handling "opened" product. Also, many manufacturers use tamper evident tape or seals to ensure the integrity of cases. Opening sealed cases negates the effectiveness of such overt security features.

It is also not uncommon for wholesale distributors to ship whole cases, or even pallets, to customers. In these circumstances, a wholesale distributor needs aggregated data from the manufacturer so that it can infer the units within when it receives and then ships an unopened case. Without aggregated data from the manufacturer, the wholesale distributor would have no ability to provide product identifiers in the TI without opening each sealed case and scanning each item. Such actions are contrary to supply chain integrity practices and are very slow, inefficient, and highly burdensome to implement.

For all these reasons, HDA strongly advocates for the ability of supply chain participants to infer contents of cases, pallets, and other aggregated containers. But in order to infer the contents of sealed cases or other containers (and subsequently be able to provide customers with product identifiers in the TI as required), manufacturers will need to aggregate serialized product packages into homogenous cases or other containers and forward the corresponding data to distributors.

Dispensers are also asking, or we anticipate will be asking, distributors to provide aggregated data to them when they receive large volume containers with individual packages. In these instances, a sealed container (*e.g.*, an unopened case, multiple products in a mixed tote) will move from the distributor to the next supply chain partner. The distributor will have to aggregate product identifiers for individual product packages within the larger container and associate those identifiers with the identifier for the larger shipping container.

[38] HDA Research Foundation (formerly the Center for Healthcare Supply Chain Research) *87th Edition HDA Factbook: The Facts, Figures & Trends in Healthcare (2016-2017).*

C. Importance of Inference and Aggregation For Compliance in 2019 and 2023

1. 2019 – Verifying Saleable Returns

As mentioned above, beginning November 27, 2019, a wholesale distributor must verify any returned product it intends to resell and a manufacturer must respond to this verification request within 24 hours (or such other time FDA establishes).[39] This verification requirement has the potential to significantly impact the U.S. pharmaceutical supply chain given that approximately 2 percent of pharmaceuticals are returned by dispensers to the wholesaler who sold them. Wholesale distributors receive approximately 58.7 million units of saleable returns per year, amounting to about 226,000 units per day. As will be discussed later, this looming verification requirement was the impetus for the HDA Saleable Returns Pilot.

There is also a critical relationship between aggregation, inference and a wholesale distributor's ability to comply with this 2019 requirement. If a wholesale distributor receives aggregated, serialized data from the manufacturer, the distributor will be able to verify the product identifier on a return even if the customer had received the unit in a sealed case because the manufacturer provided aggregated data that associated that unit's identifier to the identifier of the case that contained that unit. Without these data, the only way the wholesale distributor would be able to verify the return after November 27, 2019 would be to contact manufacturers for up to 226,000 units each day. The volume of these requests, which manufacturers must respond to within 24 hours, would overwhelm both distributors and manufacturers and severely compromise efficient supply chain operations.

While receiving aggregated data is one method to support compliance with the 2019 verification requirement for distributors, HDA recognizes that aggregation may not be the solution in every instance. Where the wholesale distributor has not received aggregated data from a manufacturer, the wholesaler will have to find another alternative for verification of saleable returns. We are supportive of alternatives that both satisfy the DSCSA's 2019 verification requirement and allow for the rapid movement of product to meet healthcare needs. For instance, the HDA Saleable Returns Pilot tested a verification router service, where a distributor captures the product identifier on a saleable return and parses the data to a third party routing service. The routing service relies upon the associated GTIN embedded in the identifier to automatically query the appropriate manufacturer database and return a verification response in real-time.

HDA welcomes support from FDA on aggregation and use of inference, and any other alternatives to them that will allow for verification of saleable returns without also interfering with the timely movement of pharmaceuticals.

[39] *See* § 582(c)(4)(D); § 582(b)(4)(C).

2. 2023 and Beyond – HDA Requests That FDA Encourage Inference and Aggregation and Provide Guidance

As discussed, HDA believes that inference and aggregation are necessary to maintain current service levels for the distribution of needed medicines to patients and healthcare providers. Allowing inference by distributors and other supply chain partners will help to facilitate implementation of the DSCSA's 2023 requirements. Inference will enable compliance with the spirit and the intent of the law – to employ technology and processes in the supply chain to permit electronic traceability at the package level – for the first time. Without inference, such technologies and processes may not be successfully deployed.

Without data reflecting the individual units aggregated into larger containers, primary distributors will have incredible difficulty implementing package level traceability. Having to open and scan all units within a sealed container will dramatically slow the movement of product. We believe the ability to meet urgent dispenser needs will be severely impacted and that patient access to needed medicines could suffer.

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Based on the foregoing, we ask FDA to undertake the following as it prepares DSCSA-mandated guidance on inference and aggregation and considers pilots and other information in preparation for compliance with the 2023 requirements:

- Issue guidance that supports and endorses the use of inference and aggregation, with reference to and inclusion of GS1 standards, as applicable;
- Address in guidance the circumstances under which aggregation is permissible;
- Recognize in guidance that when discrepancies in aggregation occur, trading partners should have business processes to address such issues and that aggregation errors between trading partners do not automatically trigger suspect or illegitimate product investigations;
- Recognize in guidance that aggregation capabilities will be evolving over time to address and minimize errors;
- Support the industry's ongoing efforts to develop exceptions handling procedures for when mismatches between product and data occur;
- Consider the need for inference and aggregation early in the Agency's own pilot activities; and
- Work with supply chain members to facilitate early adoption - preferably at the time serialization is established - so that appropriate testing may occur to facilitate compliance by 2023; early FDA involvement may also avoid manufacturers and repackagers from having to change and rework already implemented processes.

IV. HDA's Position on the Request by GPhA to Postpone the Saleable Return Verification Requirements, Currently Effective in 2019, Until 2023

At the October 14 public meeting, a speaker from the Generic Pharmaceutical Association (GPhA) asked that FDA exercise enforcement discretion and not require wholesale distributors to verify saleable returns in 2019. The primary basis for the request articulated at the meeting was that, to meet the verification of saleable returns requirement, some wholesale distributors were asking for aggregated product identifier data from manufacturers and that generic drug manufacturers could not both serialize product and provide aggregated product identifier data by November 27, 2017.

Summary of HDA's Position: We are reluctant to endorse a delay in implementation as we believe that it will also delay the movement toward data and product identifier standardization necessary to achieve 2023 interoperability.

Recommendation to FDA: Rather than delaying the 2019 verification requirement, HDA believes a better, if partial, solution would be for FDA to issue guidance supporting inference and aggregation as discussed in Section III above. Also, it would be useful if FDA were to recognize that there are alternatives to aggregation and use of inference that allow for verification of saleable returns without also interfering unduly with the timely movement of pharmaceuticals.

It should be noted that HDA, whose members will have to conduct the verification of saleable returns starting in 2019, has not requested the delay of this requirement. Moreover, wholesale distributors believe that they provide a valuable service in attempting to resell saleable returned products, rather than merely returning them to the manufacturer for disposition. Reselling verified products has significant benefits for the supply chain by reducing waste and associated costs.

HDA is reluctant to endorse a delay in the 2019 verification requirement for several reasons:

- One benefit of serialization in 2017, verification in 2019, and phasing in the sending and receipt of serialized data by 2023 is that this step-wise approach recognizes that serialization and full data (including product identifiers in TI) will not occur with a "flip of the switch." Spreading out the implementation milestones eases the burdens of implementation and allows more unserialized product and serialized product without data to move out of the supply chain as serialized product with data moves into distribution.
- Verification of saleable returns serves as an additional security function – it is intended to help prevent illegitimate product from entering the supply chain by imposing greater controls upon the returns process.
- Delaying verification until 2023 may stall the movement toward standardization of product identifiers and associated data. We are uncertain whether the short term benefits of delaying verification will be worth the future burdens upon systems and processes.

- The HDA Saleable Returns Pilot, as discussed briefly in Section VIII below, identified potential methods for meeting the 2019 requirement for verifying saleable returns without aggregation.

We believe that, to the extent the request for a delay in verification is driven by concerns over accuracy of transmitted aggregated product data, the better solution would be for FDA to assure the supply chain that authorized trading partners may work together to resolve any product and data mismatches without automatically triggering suspect and illegitimate product notifications or other concerns. In this way, the progress toward 2023 interoperability continues and trading partners are able to begin working out how inference and aggregation will work in the DSCSA environment.

Also, given the concerns expressed that some manufacturers may not be able to aggregate by 2019 given the significant demands of serialization, HDA believes that the Saleable Returns Pilot (discussed in Section VIII) offers useful learnings. The Saleable Returns Pilot tested different alternatives for verification of saleable returns, including one that involved the use of a third-party verification router service to query a manufacturer's product identifier database.

In weighing whether or not to grant GPhA's request, HDA offers the following for FDA's consideration:

- HDA asks that FDA weigh the potential negative consequences that may come from delaying standardization of the product identifier and associated data.
- HDA asks that FDA also consider the burden of compressing the timeframe in which serialization, aggregation, inference and interoperable data exchange must all occur, particularly given that the DSCSA adopts a phased-in, step-wise approach.
- If FDA elects to grant the requested enforcement discretion, it is imperative that the announcement be made as soon as possible. Systems cannot be changed quickly and many stakeholders are moving forward with serialization, aggregation, and changes to operations and business processes to conduct verification of saleable returns.
- As we believe that some of the concerns regarding aggregation reflect uncertainty about how FDA will treat otherwise routine aggregation discrepancies, we urge issuance of a guidance supporting inference and aggregation that also supports allowing authorized trading partners to resolve data and product mismatches internally through established business processes.

V. The Supply Chain Urgently Needs FDA to Issue Licensure Regulations

At the public meeting, HDA and other stakeholders described the problems that are arising and worsening because FDA has not issued the licensure standards for wholesale distributors and third-party logistics providers (3PLs). We addressed this issue in our prepared statement and expand upon those remarks here.

Summary of HDA's Position: The DSCSA was intended to bring national uniformity to licensure requirements. In the absence of federal standards, a patchwork of different and inconsistent requirements is developing in the States and creating numerous problems for stakeholders.

Recommendation to FDA: While we understand that FDA is working on the licensure standards and appreciate the Agency's diligent efforts, we ask that the Agency promulgate the standards as quickly as possible. The rulemaking process is likely to be extensive and lengthy. Stakeholders will need time to absorb and comment on FDA's proposals and FDA will need additional time to finalize the standards. The process of adoption could be complicated for States that will have to change their statutes, particularly as most State legislatures meet only once a year, for a short period of time.

A. The DSCSA was Supposed to Bring National Uniformity to State Licensure

HDA addressed its views on the importance of national uniformity in licensure standards in our December 2014 comment submitted to Docket No. FDA-2014-D-1411, *The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Draft Guidance for Industry; Availability*.[40] We will not repeat the arguments presented in our December 2014 comment except to emphasize that Congress unequivocally intended, and so specifically stated in the DSCSA, that wholesale distributor and 3PL licensure standards were to be uniform, national, and established by FDA, and were to preempt State requirements.[41] The absence of federal licensure standards, however, is raising additional concerns:

- Resource-constrained State pharmacy boards that chose to implement the DSCSA without the benefit of the federal standards will likely have to go back and redo their codes once FDA releases the federal standards;
- Believing that their own laws and regulations persist, some States are continuing to permit activities that the DSCSA was intended to stop, such as dispensers acting as wholesalers without obtaining appropriate licenses or complying with the DSCSA's data and other requirements in § 582;
- Some States are imposing requirements that are contrary to and more burdensome than what the DSCSA requires; and
- For wholesale distributors and their advisors and consultants, there are only a limited number of people who possess the necessary expertise to guide the industry into the 2019 and 2023 requirements. The same people that are wrestling with State licensure inconsistencies are also deeply involved with every other part of their companies' implementation of the DSCSA. Dealing with State licensure

[40] HDA's comment is available here, https://www.regulations.gov/document?D=FDA-2014-D-1411-0010.

[41] *See* § 585(b)(1) which provides for the preemption of any State requirements "with respect to" wholesale distributor licensure that are "inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under §503(e)." In turn, §503(e) mandates the establishment of federal requirements that States may then adopt; each such federally and State-issued license "***shall*** meet the standards, terms, and conditions established by the Secretary under section 583."

requirements that are inconsistent with each other and with the DSCSA should not be the distraction that it has become.

B. Examples of State Problems

While some States are waiting for FDA to publish the new DSCSA licensure standards before making any changes to their laws and regulations, others are adopting different provisions or are continuing to permit activities that the DSCSA halted and preempted. Examples include the following:

- The different requirements regarding 3PL licensure have created irreconcilable conflicts between the DSCSA and State law. One State has established a 3PL license and requires a non-resident 3PL to prove it is licensed by its own home State *as a 3PL*. However, many States are either still licensing 3PLs as wholesaler distributors or not licensing 3PLs at all. As a result, these entities are unable to obtain an out of state license from the State they are shipping into.[42]
- A State effectively requires manufacturers that distribute their own drugs to be licensed as a wholesale distributor in the State, which is in conflict with the DSCSA.[43]
- A State has been telling wholesalers and manufacturers to reprint TI documents with the state-licensed location (*i.e.*, shipping point) rather than the seller's corporate location. However, the DSCSA requires TI to include the name and address of the party transferring ownership of the product which is frequently the seller's corporate location, not the state-licensed shipping location.
- A State is mandating recordkeeping requirements not required by the DSCSA.
- Recently, one State Board of Pharmacy (BOP) sent a letter to licensees describing its initial plans for DSCSA implementation activities. The preliminary terms and definitions the BOP put forth did not match the DSCSA and would require entities to hold registrations that FDA simply does not issue or recognize. The proposals would also allow for sales the DSCSA was intended to stop, such as the so-called "5 percent rule" which permits up to 5 percent of a pharmacy's sales to be to other pharmacies without it being classified as a wholesale distributor.

VI. FDA Guidance on GS1 Standards is Needed for Wide Scale Adoption in the Supply Chain

Summary of HDA's Position: Insofar as the product identifier and eventual interoperable, electronic exchange of data are concerned, many – and maybe most – members of the supply chain have assumed that they should look to GS1 standards. This includes the evolving GS1 Electronic Product Code Information Services (EPCIS) standard to support the exchange of transaction data between trading partners, having the product identifier include a serialized Global

[42] § 585(b)(2) and § 503(e)(5) prohibit a State from regulating a 3PL as a wholesale distributor.

[43] § 503(e)(4)(H).

Trade Identification Number (GTIN) assigned in accordance with GS1 standards, and use of GS1-assigned Global Location Numbers (GLN) as appropriate location identifiers. However, FDA has not specifically expressed its support for these standards.

Recommendation to FDA: HDA asks that FDA, as soon as possible, in guidance,

- Acknowledge GS1 as an appropriate international standard-setting body under the DSCSA;
- Support the GS1 EPCIS standard for the exchange of transaction data;
- Announce a preference for a product identifier that includes a serialized GTIN and that a product's NDC number should be converted to a serialized GTIN in accordance with GS1 standards;
- Support a GS1 standard for GLNs, the use of a GLN to identify a location, and reliance upon GLN master data associated with that GLN; and
- Support the use of the HDA guideline on the appropriate placement of 2D data matrix barcodes on products and cases to ensure that they are readable**.**

A. EPCIS

In the November 2014 Draft Guidance, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information*, FDA recognized that, for the first exchanges of transaction data that were to begin January 1, 2015, trading partners could use one of five methods for the exchanging:

- Paper or electronic versions of invoices;
- Paper versions of packing slips;
- Email or Web-based platforms (such as Web portals);
- Electronic Data Interchange (EDI) standards, such as 856 Advance Ship Notice (ASN); and
- EPCIS (Electronic Product Code Information Services).

The standards for the interoperable exchange of data "shall comply with a form and format developed by a widely recognized international standards development organization."[44]

EPCIS is a widely used standard established by GS1, an international standards setting organization. HDA members believe EPCIS is the only standard currently in use that could accomplish DSCSA goals. HDA strongly urges FDA to recognize and expressly support the use of EPCIS as the preferred method for achieving 2023 electronic interoperability between trading partners. FDA's explicit support for the EPCIS standard would give the industry confidence to begin the changes and investments necessary to move toward wide-scale adoption. If FDA identifies EPCIS as the preferred standard, we request that FDA also support two required data elements for EPCIS – the GTIN and the GLN. We also encourage FDA to indicate that paper

[44] §582(a)(2)(A).

invoices and packing slips do not meet the definition of the "interoperable, electronic" system required by 2023 under § 582(g)(1).

B. GTINs and Product Identifiers

As discussed at the public meeting, industry is proceeding with serialization of products and, in the experience of HDA's members, most are adopting a serialized GTIN as part of the product identifier, assuming that FDA will conclude that it complies with the DSCSA. In its Guidance for Industry, *Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages* (March 2010) (*SNI Guidance*),[45] FDA supported a serialized NDC number that is compatible with, and may be presented within, a GTIN. This Guidance, however, predates the DSCSA and FDA has never specifically stated that a serialized GTIN (plus lot number and expiration date) meets DSCSA requirements for product identifiers.

Moreover, as discussed at the public meeting, even though there is a GS1 standard for GTIN assignment, there continues to be much confusion about how to convert a product's NDC into a serialized GTIN, even with the availability of the SNI Guidance. Inconsistencies in presentation of expiration dating are also a concern when they are added to the product identifier.

HDA and its members believe that industry movement to a standardized product identifier would be enormously aided if FDA revised the SNI Guidance, or issued a new DSCSA-specific guidance, that explicitly addresses the following:

- A serialized GTIN, compliant with GS1 standards, may be incorporated into a product identifier and be deemed compliant with the DSCSA;
- How to convert and incorporate an NDC into a GTIN, with endorsement of the GS1 standard**;**
- How to format the human-readable component of the product identifier; and
- How to format, present and incorporate expiration dates and lot numbers in a product identifier.

C. Global Location Number (GLN)

In addition to depending upon GTINs, EPCIS also relies upon GS1-assigned GLNs which enable companies to consistently and transparently identify their locations in this abbreviated numeric fashion. HDA previously supported movement to GLNs in its comments submitted after the Pilots Workshop in April 2016 [46] and we reiterate that support here. If EPCIS becomes, as we

[45] http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf

[46] "A GLN is crucial to EPCIS … A supply chain participant must have a GLN to participate in EPCIS." Comments of the Healthcare Distribution Management Association on 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.

believe it should, the preferred vehicle for interoperable, electronic exchange of transaction data between trading partners in 2023 and beyond, it will be necessary for trading partners to move to the use of GLNs to identify their locations.

HDA urges FDA to

- Expressly support the use of GLNs as an appropriate location identifier; and
- Recognize that transmission of the GLN within TI would fulfill the DSCSA's requirement to provide ownership name(s) and address(es) by reliance upon GLN master data associated with that GLN.

D. Guidance on 2D Data Matrix Barcode

During the October 14 public meeting, HDA members presented some of the issues that are currently being observed in the marketplace with the barcodes affixed on product packages and cases. These problems underscore an important issue. Specifically, a manufacturer could expend enormous resources to serialize products and affix 2D data matrix barcodes, only to find that a downstream customer is unable to read the barcode. HDA manufacturer and wholesale distributor members have collaborated to develop *Guidelines for Bar Coding in the Pharmaceutical Supply Chain Quick Start Guide*, ("Guide").[47] This Guide provides assistance in how to serialize a product, create a 2D data matrix barcode, and affix that barcode to assure maximum readability. HDA is also working to include additional recommendations for standardization based on the Saleable Returns Pilot study results.

FDA support for the HDA Guide would be very helpful in moving more trading partners to a standardized format for presentation and affixing of barcodes on products and cases.

VII. FDA Should Clarify that a Data Error is Not Necessarily an Indication of a "Suspect" or "Illegitimate" Product

HDA and other members of the supply chain have previously pointed out to FDA that it is a commercially normal event for there to be occasional mismatches between product shipped/received and the associated transaction data. The issue was also discussed above in Section III.C.2 in the context of aggregation. Supply chain members have explained that such events should not automatically trigger a suspect product investigation,[48] but should first be resolved by trading partners pursuant to normal business practices and exceptions handling guidelines.

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[47] The Guide is publicly available free of charge at https://www.healthcaredistribution.org/publications/hda-guidelines-for-bar-coding-in-the-pharmaceutical-supply-chain-quick-start-guide.

[48] *See, e.g.*, HDMA/HDA comments to FDA on "*Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*," 79 Fed. Reg. 33564 (June 11, 2014), Docket No. FDA-2014-D-0609.

Summary of HDA's Position: During regular transactions between authorized trading partners, there will be instances where product and data do not match, including in transactions where individual units have been aggregated to a larger container and do not match the aggregated serialized data the manufacturer sent to the distributor. Mismatches are inevitable given the immaturity of the processes and the volume of product that rapidly moves between authorized trading partners. In these mismatch and other similar types of situations, HDA believes neither FDA nor any trading partner should immediately categorize the associated product as "suspect" or "illegitimate." Trading partners should have business processes in place to resolve such issues.

Recommendation to FDA: HDA urges FDA to

- Clarify in any related guidances the distinction between exceptions and issues that may arise from verification and aggregation processes versus true concerns;
- Clarify that a mismatch between product and DSCSA-related data does not automatically render a product to be suspect; and
- Encourage trading partners to have robust Standard Operating Procedures for the varieties of possible scenarios in which data and product identifiers do not match precisely, including methodologies and processes for how trading partners may resolve such discrepancies.

VIII. The HDA Saleable Returns Pilot and Manufacturer Serialization Readiness Survey

As we noted in our verbal statement on October 14, for well over a year, HDA has been sponsoring the Saleable Returns Pilot to examine different methods for verifying product identifiers on saleable returns in an effort to better understand the operational impact of the 2019 DSCSA requirements, and how the industry can best meet these requirements. HDA's Traceability Pilot Work Group (TPWG) members, consisting of both wholesale distributor and manufacturer members, have been providing guidance based on their extensive expertise, and are fully participating in this Pilot.

The objectives of the Saleable Returns Pilot were to gain first-hand, real-world experience with the processes and technologies required to effectively manage saleable returns from the dispenser to the distributor, and coordinate the mandated verification of product identifiers with the manufacturer. A description of the compliance scenarios which were included in the Pilot is available here: http://www.hda.org/~/media/pdfs/industry-relations/hda-pilots-scenario-brochure.ashx The Pilot report is close to finalization. Upon completion, HDA will provide a copy of the final report to inform those who seek a better understanding of how processes and technology could be used to efficiently and effectively implement this requirement.

In addition to the Pilot, HDA has recently conducted a survey of manufacturers to obtain a better understanding of the flow of serialized product and data to wholesale distributors in preparation for meeting the November 27, 2017 milestone. The questions were intended to include both internal manufacturing lines and contract manufacturing.

HDA has completed the survey and is pleased to include a link to the "Manufacturer Serialization Readiness Survey" report located here: http://www.hda.org/~/media/pdfs/industry-relations/manufacturer-readiness-survey-results-report.ashx

Recommendation to FDA: We urge FDA to review the 2019 Saleable Returns Pilot and Readiness Survey reports to help inform any further support that the Agency may provide with regard to implementing the returns verification requirements effective in 2019 and beyond.

IX. DSCSA Implementation - Focus Upon Building a System

Some participants at the FDA public meeting expressed concern about building systems to support industry compliance with 2019 verification requirements if such systems are going to be discontinued ("thrown-away") by 2023 as non-compliant or redundant once trading partners include product identifiers in TI. HDA and its members share this concern. It was argued that some companies would find it more efficient to create a single system, once, that could both verify saleable returns in 2019 and be built upon and scaled up to meet the DSCSA's interoperability requirements for 2023.

Indeed, in the context of the Saleable Returns Pilot, one criterion for a tested model's success was whether Pilot participants deemed that the particular model could meet both 2019 verification requirements ***and*** continue to be useful in 2023. DSCSA implementation is complex and costly; the supply chain benefits if trading partners only have to make major systems changes and investments once.

Summary of HDA's Position: Based upon the limited experience with the Saleable Returns Pilot, the multiple verification options, and the many supply chain participants (both wholesale distributor and manufacturer) with differing requirements and capabilities, HDA does not believe that a complete picture of a desirable system architecture for 2019 or 2023 has yet developed. We plan to continue assessing these important questions and working with HDA members and FDA as a clearer picture of 2023 interoperability develops.

Recommendation to FDA: HDA recommends that FDA continue its collaboration with the supply chain to assess 2019 and 2023 systems and announce as early as possible if the Agency sees approaches that it views as out of alignment with the Agency's own DSCSA requirements.

X. Guidances on Grandfathering, and on Waivers, Exceptions and Exemptions

Summary Of HDA's Position: In prior communications with FDA, HDA and other members of the supply chain have urged the Agency to issue the guidances on grandfathering and waivers, exceptions, and exemptions mandated by § 582(a)(3) and (5). HDA appreciates FDA's statements from the public meeting that the Agency recognizes the importance of the guidances and that it expects to release them soon.

Recommendation to FDA: There remains a pressing need for FDA to issue these guidances so that supply chain members can continue their compliance efforts in an expeditious and efficient manner.

With respect to the grandfathering guidance, HDA emphasizes that wholesale distributors are cognizant of the fact that beginning November 27, 2019, they may not engage in transactions involving a product without an identifier unless that product is grandfathered or otherwise the subject of an FDA-granted waiver, exception, or exemption. The absence of the grandfathering guidance is creating uncertainty regarding systems design and redesign, and concern regarding how to distinguish grandfathered product from product that is non-compliant with identifier requirements.

In prior comments HDA submitted to FDA,[49] HDA stated the following regarding the grandfathering guidance:

> … though manufacturers must begin serializing product by November 27, 2017, wholesale distributors may continue to transact with unserialized product for two more years, until November 27, 2019. This two-year gap – which aligns with the expiration dating of many drugs – will allow much unserialized product to be used and dispensed before the 2019 deadline. However, HDMA believes that over 30 percent of prescription products have expiration dating beyond two years, which means that some unserialized, saleable products will still be in commerce in 2019. Additionally, even if the product bears the identifier, that product identifier does not need to be included in the seller's transaction information (TI) until November 27, 2023. Thus, for many years, distribution will be complicated by the fact that trading partners will be concurrently transacting with serialized and unserialized products and even if product is serialized, the identifier does not need to be included in TI until 2023.
>
> The grandfathering guidance could ease these implementation challenges that the DSCSA's phased-in timeline poses. The grandfathering guidance will also need to recognize that permitting product to circulate without serialized identifiers and/or data has a "ripple" effect as that product moves, over a period of months or years, from the manufacturer through the wholesale distributor to the dispenser and, possibly, back as a saleable return.

The points made above remain important and HDA looks forward to working on their resolution with FDA.

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[49] Comments by the Healthcare Distribution Management Association on the FDA Federal Register Notice "*Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information*" 81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114, May 16, 2016.

HDA and others in the supply chain have also urged issuance of the FDA guidance required by § 582(a)(3) to establish processes by which the Agency can review and respond to requests for waivers, exceptions and exemptions from DSCSA requirements. As we explained previously:[50]

> There is an urgent need for a documented, transparent process for review of DSCSA waivers, exceptions and exemptions…. These are all very important decisions. We believe that the process for seeking waivers, exceptions and exemptions from the DSCSA would be significantly aided by clear agency guidance on the processes to follow.

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Conclusion

HDA thanks FDA for the opportunity to provide input to the Agency as it considers implementation of the DSCSA. Should you have any questions about these comments, please feel free to contact Anita Ducca, Senior Vice President, Regulatory Affairs at 703-885-0240 or aducca@hda.org.

[50] Comments by the Healthcare Distribution Management Association on the FDA Federal Register Notice *Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information*, 81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114, May 16, 2016.