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Healthcare Distribution Alliance

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RE: Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments Dkt. No. FDA-2017-N-3857

Dear Dr. Jung:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding Enhanced Drug Distribution Security under the Drug Supply Chain Security Act; Request for Comments, 82 Fed. Reg. 33505 (July 20, 2017), Dkt. No. FDA-2017-N-3857 ("Request for Comments").

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

I. OVERVIEW

HDA appreciates FDA's plans to sponsor public meetings and opportunities for participation and comment on enhanced security under the Drug Supply Chain Security Act (DSCSA). The recent August 23 public meeting was intended to address issues regarding 2023 supply chain security and enhanced drug distribution security needs. HDA offered brief comments at the August 23 public meeting. Here, we expand upon those comments and further address issues raised during that meeting. In particular, HDA:

- Urges focus upon what ***must*** be accomplished to achieve 2023 compliance;

- Summarizes our previously presented interpretation of the DSCSA's 2023 requirements in an enhanced, interoperable electronic system for drug product tracing;
- Discusses potential challenges to creating and adopting a centralized system;
- Addresses concepts and terminology raised at the August 23 public meeting, including "status" of a product and data access; and
- Offers suggestions for the upcoming December 5 and 6, 2017 public meeting.

II. A SAFE, SECURE AND INTEROPERABLE SYSTEM FOR DRUG PRODUCT TRACING FOR 2023

A. HDA Urges Focus on the DSCSA's 2023 Requirements First

On November 27, 2023, in order to comply with § 582(g)(1)(A), for each transaction (*i.e.*, change of product ownership), the "selling" authorized trading partner must send transaction information (TI), including product identifiers, and a transaction statement (TS) (but not transaction history (TH)), to the "purchasing" authorized trading partner in a secure, interoperable, electronic and standardized manner. To be able to meet this deadline, FDA and stakeholders must align on the basic elements for DSCSA compliance – what interoperable means, how to make a system interoperable, who sends data, who receives data, what data must be sent and in what format, and what international standards apply to this exchange. Establishing this interoperable system is also a prerequisite to being able to meet other requirements of § 582(g)(1), such as being able to respond to appropriate requests for TI and TS in a recall or suspect product investigation.

During the August 23 public meeting, much of the discussion seemed centered around the things an interoperable electronic system for tracking pharmaceuticals theoretically ***might do***, without sufficient explanation of ***what an interoperable system is*** and what it ***must do*** by November 27, 2023. HDA recognizes the appeal of aspirational features of this system and fully supports trading partners voluntarily exploring additional functionality.

However, with 2023 requirements still to be met and transaction data that must be exchanged seamlessly between trading partners throughout all sectors of the supply chain, we believe focus upon potential, future capabilities is distracting from the considerable work that must be done, particularly item-level serialization, verification, serialized data exchange, and providing certain transaction data upon request by an appropriate entity. Wholesale distributors look forward to exploring with their trading partners the potential additional opportunities interoperability provides, though not at the risk of sacrificing compliance with the DSCSA's requirements by 2023.

B. HDA's View of an Enhanced, Interoperable Electronic System in 2023

HDA previously provided detailed comments describing its interpretation of the enhanced, interoperable electronic system for drug tracing required by the DSCSA in § 582(g). Our comments, submitted on November 14, 2016 to Dkt. No. FDA-2016-N-2673 are available here. We briefly reiterate some of the key points.

The traceability model the DSCSA builds for 2023 and beyond is significantly more protective than the current state, and far more protective than what existed prior to the DSCSA's enactment. By

November 27, 2023, each package of applicable product must bear a unique product identifier.[1] When transferring ownership of a product, each authorized trading partner must provide TI, including the product identifier for ***each and every unit*** in the transaction,[2] and TS to its customer, who, in turn, will provide its own TI and TS to its subsequent customer, in each instance with the TI reflecting the current ownership and sale. These transaction data are to be communicated in an interoperable exchange ***between*** the seller and the buyer, under standards "that comply with a form and format developed by a widely recognized international standards development organization."[3] These transaction data are the private, proprietary records of the respective selling and buying trading partners.

It is important to remember that, even beyond the new transaction data exchange requirements effective in 2023, the DSCSA mandates additional important layers of protections:

- Trading partners must be "authorized."[4]
- Direct purchase statements must be provided when applicable and serve as attestations that the seller either purchased directly from a manufacturer, or purchased from a seller who purchased directly from a manufacturer,[5] which means there are added assurances of product safety and integrity.
- Each trading partner will be able to identify, by unique product identifier for each product, the TI for its purchase and sale of that product, including identification of its supplier and customer, and when it purchased and sold the product.[6]
    - With this visibility, each trading partner will be able to quickly produce a product's TI in order to facilitate the FDA or other appropriate official's gathering of the product's TI back to the manufacturer in recalls and suspect and illegitimate product investigations.[7]
    - Additionally, each trading partner will be able to promptly respond to appropriate requests with both the product's TI and the seller's TS that attests, among other things, that the product (to the seller's knowledge) is not suspect or illegitimate, and that the seller is authorized.[8]

The DSCSA builds over its ten-year implementation a highly protective, secure, interoperable system between trading partners that significantly enhances supply chain security over the pre-2013, pre-DSCSA state.

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[1] § 581(14) (definition of product identifier); § 581(20) (definition of SNI); § 582(b)(2).
[2] § 582(g)(1)(B).
[3] § 583(h)(4)(A)(i). HDA assumes these will be GS1 standards as they are, currently, the only ones capable of supporting the exchange of the data in the manner specified by the DSCSA.
[4] § 581(2) (definition of authorized); § 581(23) (definition of trading partner); §§ 582(b)(3), (c)(3), (d)(3), (e)(3) (trading partners of manufacturers, wholesale distributors, dispensers and repackagers, respectively, must be authorized). The requirements regarding transactions only with authorized trading partners have been in place since January 1, 2015.
[5] § 582(c)(1)(A)((ii)(I)(aa)(AA); § 582(c)(1)(A)(iii). An exclusive distributor or repackager that purchases directly from the manufacturer must also provide a direct purchase statement attesting to subsequent buyers that it purchased directly from the manufacturer. 582(c)(1)(A)((ii)(I)(aa)(AA). The requirements regarding direct purchase statements have been in place since January 1, 2015.
[6] § 582(g)(1)(A)-(B); § 581(26) (definition of TI).
[7] § 582(g)(1)(E).
[8] § 582(g)(1)(A),(D); § 581(27) (definition of TS).

C. Clarification of the Proposed Definition of "Interoperability"

In the *Concepts and Terminology* document FDA released prior to the public meeting, the Agency defined "Interoperability" as follows:

> Interoperability is the ability to exchange information accurately, efficiently, and consistently ***among*** trading partners. [Emphasis added]

HDA has reservations concerning this proposed definition of "interoperability." Despite the DSCSA's clear requirement that a trading partner must produce the TI from its own individual purchase and/or individual sale of that product upon appropriate request, we believe that use of the term "among" rather than "between," may be misinterpreted as suggesting that interoperability means the ability to exchange or view transaction data beyond the two immediate trading partners to the transaction. Exchanging data "among" trading partners could inaccurately be interpreted to encompass end-to-end visibility of all of a product's entire transaction data that had been exchanged throughout the supply chain. We believe the term "among" rather than "between" could suggest that a manufacturer should be able to look downstream at its customers' transactions, and enable dispensers to look back to a manufacturer's first sale and view the product's entire TH.[9]

We believe the definitions of "trading partner" and "transaction" support our interpretation that the DSCSA contemplates only the retrieval upon appropriate request of the TI (or TI and TS) that has been exchanged between two trading partners and is held by those trading partners, not end-to-end visibility into all product transaction data. The definition of trading partner in § 581(23) contemplates only two entities in a transaction (change of ownership) of a product: "'trading partner' means … ***a*** manufacturer, repackager, wholesale distributor, or dispenser from whom ***a*** manufacturer, repackager, wholesale distributor, or dispenser ***accepts*** direct ownership of a product or to whom ***a*** manufacturer, repackager, wholesale distributor, or dispenser ***transfers*** direct ownership of a product" (emphasis added). Similarly, "transaction" in § 581(24) is defined as "the transfer of product ***between*** persons in which ***a*** change of ownership occurs" (emphasis added).

Thus, the definitions of "trading partner" and "transaction" both assume only a single acceptance of ownership (by a buyer) and a single change/transfer of ownership (by a seller). By their express terms, "trading partner" and "transaction" do not include any previous seller or subsequent buyer, or any previous sale or subsequent sale. Each trading partner should be able to engage in DSCSA-compliant, consistent, efficient interoperable transactions with all its trading partners; this does not mean that a single trading partner can, or is entitled to, view the transaction data beyond the immediate, single transaction to which it was a party. We accede to the proposed definition of "interoperability" so long as it is not interpreted to mean end-to-end visibility into all of a product's transactions from any point in the supply chain.

D. FDA's 2023 Vision of a Centralized Interoperable Electronic System

The vision FDA articulated at the August 23 public meeting seemed more aspirational than the DSCSA-required system described above. It appears FDA envisioned a system that could provide all information on a product, from point of commissioning the identifier to point of dispensing. Such a system appears to presume that each trading partner in the supply chain would make its transaction data available, via an upload to a central database, or routers to interconnected databases, or some other means.

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[9] We believe such an interpretation attempts to preserve TH when the DSCSA expressly eliminates its. TH sunsets and drops from DSCSA requirements automatically, by operation of law, on November 27, 2023. § 582(k)(1).

E. Potential Challenges to Creating and Adopting a Centralized System

HDA supports efforts by supply chain members to explore, eventually, all the many potential functionalities that item-level serialization and interoperability might bring. However, we believe that present discussions should be focused on all that must still be accomplished in order to meet 2023 compliance obligations. Though a centralized system may permit functionalities beyond what the DSCSA requires, we have identified the following potential challenges to creating and adopting such a system between now and 2023, and possibly thereafter:

- Creation of a centralized system at this juncture would be very complex, particularly in the absence of any governmental authority to develop, manage, and fund one.[10] Stakeholders would have to bear the costs and liabilities to develop, design, build and manage it. Data access, ownership and security would also pose significant hurdles, particularly since transaction and product identifier data residing in a centralized database or connected databases would be a temptingly lucrative target for counterfeiters and hackers. In part because of the volume of participants, including dozens of wholesale distributors, hundreds of manufacturers, and hundreds of thousands of dispensers, we anticipate obtaining industry-wide participation in such a system, and governance of it, to present ***very*** significant challenges.

- A centralized system with the ability to see and know a product's status at any point in the supply chain would also require trading partners to undertake actions the DSCSA does not mandate. The system's ability to find all information about any product with a single query assumes that every trading partner is participating in the system and either uploads data to it, or permits connections to its own data repository. It is difficult to see how any such centralized system could provide meaningful, accurate data unless all trading partners were legally required to participate in it. We do not believe such a requirement can be found in the DSCSA.

    - Having visibility into where a product has been in the supply chain would appear to be an effort to capture a product's TH back to the original manufacturer in a single scan of a product identifier. However, TH sunsets and drops from DSCSA requirements automatically, by operation of law, on November 27, 2023, when the requirements relating to TH "shall have no force or effect."[11]

    - Had Congress intended the enhanced interoperable system to provide end-to-end visibility into where a product has been with a single scan, it had a model in California's electronic pedigree law, SB 1307.[12] Unlike 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.[13]

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[10] We believe that supply chain members in foreign countries using central data repositories typically have a governmental entity assigned to manage such repositories and a defined source of funding to support them. Additionally, we believe that these systems usually are smaller than what FDA appears to have contemplated, do not include transaction data and are more narrowly focused upon checking by dispensers prior to dispensing. In sum, such systems have a governmental authority to support them and a construct that assumes both a much narrower set of data, and a different use of such data – concepts that are not in the DSCSA.

[11] § 582(k)(1).

[12] 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. *See* § 2 of SB 1307.

[13] § 585(b)(1).

- 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."[14] We do not believe "facilitate gathering" supports access to all product information in a centralized database or across databases. By its clear and express terms, the DSCSA ***does not require*** the 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. 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 and only in recalls and suspect and illegitimate product investigations.

- Last, though wholesale distributors have been and are committed to implementing the DSCSA and to its goals of better serving patients through a secure, efficient, compliant, supply chain, the enormous work done so far does not contemplate building a centralized model which is what we believe would be necessary to accommodate the many additional, but not required, features discussed at the August 23 meeting. There would be very significant consequences to diverting scarce resources to building such a model now.

  - As the entity that sees "both sides" of most pharmaceutical transactions, wholesale distributors have to develop the systems and processes with their manufacturer suppliers and with their dispensing customers to keep medicines flowing to the patients who need them. To accomplish all that has been done already has required very significant investments in human, capital and technological resources. Moreover, achieving each DSCSA milestone so far has taken longer and proven to be more complex and costly than anticipated.

  - While recognizing that technology can change, given the complexity of the DSCSA, the resources required to develop, test and implement each step, and the importance to public health of continued supply of safe pharmaceuticals, trading partners are making decisions now, or have already made decisions, that are necessary to comply with the 2023 requirements. Work already undertaken includes standards development to receive and provide electronic data, the creation of connections with suppliers and customers, and how to serialize products and verify product identifiers. The optional attributes FDA described at the August 23 public meeting offer potential for future applications, but are not part of the systems development going on now for 2023.

  - HDA and its members have not had any reason to focus upon development of a centralized system, though the aspirations FDA expressed at the August 23 meeting likely could only be realized through a centralized system. The issue has been raised in previous comments and testimony but, before now, we do not believe the Agency has ever expressed the expectation that one would be built. We have never interpreted the law as requiring such a system, particularly since the DSCSA is very specific about where a centralized database is required, *e.g.,* wholesale distributor and third party logistic provider (3PL) submission of state licensure information to FDA. As mentioned in footnote 10, in other countries, a centralized system has been clearly delineated in law with authority given to a governmental entity to implement and fund the system; the DSCSA contains no such authorization. One reason that the California electronic pedigree law, SB 1307 was preempted and replaced by the DSCSA was because what it mandated did not align with supply chain capabilities. For all these reasons, HDA's members, and, as we understand, other supply chain members, have been proceeding on

[14] § 582(g)(1)(E).

the assumption that they would meet the 2023 requirements using methods other than a centralized model and have been diligently working to achieve compliance on that basis.

- We continue to believe that the supply chain is best served by doing first what must be done – achieving interoperable data exchange between two trading partners with each trading partner owning and maintaining its data in a repository it controls – before trying to build something far more complex, and more expensive. Attempting to add extra attributes now will divert valuable, and limited, expertise and resources to other tasks extraneous to meeting DSCSA requirements and may actually delay implementation of the well-defined supply chain security improvements Congress has mandated take place by 2023. We believe altering course to a centralized system – which is what would be required for many of the additional functionalities – would entail enormous additional costs and significant delays.[15]

III. EXAMINATION OF CERTAIN CONCEPTS AND TERMINOLOGY

FDA released two documents called *Concepts and Terminology* and *Discussion Topics* before the August 23 public meeting. We explain below our concerns about some of the definitions in that document and, where appropriate, offer alternative language.

A. "Status" of a Product

The *Concepts and Terminology* document includes the concept of "status" of a product:

> The description of the package as it is distributed through the supply chain (e.g., recall in process, in transit, destroyed, dispensed, stolen, etc.).

The *Discussion Topics* proposed the following attribute for a "drug distribution system":

> Provides the status of a product through the use of the product identifier (e.g., "dispensed" or "expired")

The DSCSA does not mandate the capture or reporting of a product's status as it moves through the supply chain. The distributor is not required under the DSCSA to report to the manufacturer when it sells a product to a buyer, or otherwise sends the data for the transaction anywhere other than to its buying customer. Similarly, dispensers do not have to record, maintain, or verify identifiers when they administer or dispense a product.

The reporting of changes to a drug's "status," such as whether it has been dispensed, seems to presuppose the existence of a means to post or push that notice of the change, electronically, back up the supply chain. Such a theoretical capability then leads to significant additional issues, including that, to our knowledge, this systems capability and connectivity does not currently exist, particularly at the pharmacy level. We believe such a posting system would likely require the creation of hundreds of thousands of new connections the DSCSA does not require.

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[15] We also believe that the challenges and costs of implementing a centralized system or interconnected databases outweigh its benefits given the limitations the DSCSA places on access. A trading partner must produce its TI or TI and TS only in recalls and suspect and illegitimate product investigations. § 582(g)(1)(D) and (E). Also, the vast majority of product transactions are direct purchase transactions (manufacturer or manufacturer's exclusive distributor to a wholesale distributor to a dispenser). Thus, in most cases where transaction data is needed, FDA will be able to obtain all the data that exists for the product by asking only one (or two) entities to supply it.

Additionally, the DSCSA does not require that wholesale distributors, repackagers and dispensers report identifiers to any entity when sending expiring and non-saleable products to returns processors. Nor does the statute require returns processors to report product identifier information to any entity. It is possible that, with item-level serialization, contractual arrangements will arise between trading partners and/or with reverse processors for reporting the "status" associated with the product identifier data. However, this potential future information exchange would serve a business rather than a compliance purpose.

Finally, the accuracy of any "status" information assumes all trading partners record and report all changes to a product's status. In the absence of a DSCSA mandate, it is difficult to envision the entire supply chain participating in such a voluntary effort.

HDA strongly recommends deletion of the term "status" and its definition.

B. Access to Product Data

During the August 23 public meeting, FDA contemplated rapid access to, use of, and visibility into product data, theoretically, to support FDA and regional responses to investigations and recalls, further public health, or to potentially aid in allocation of inventory in shortage situations. These are functionalities that industry members may voluntarily seek to implement, while recognizing that the DSCSA limits transaction data access. Specifically, § 582(g)(1)(D) and (E) permit FDA or other governmental authority's access to a trading partner's TI or TI and TS in recalls and suspect and illegitimate product investigations. These are the only circumstances where the DSCSA permits access to transaction data.[16]

Moreover, should FDA become concerned about a product, the Agency may obtain additional records from regulated entities through its traditional inspectional and enforcement authorities under the FDC Act and implementing regulations.

C. Trading Partner Authorization

In the *Discussion Topics,* and during the public meeting, FDA posed questions regarding whether a system that provides enhanced drug distribution security should be able to "verify" that a trading partner is an "authorized" trading partner. This functionality is beyond the DSCSA's requirements, and we do not believe this is a reasonable expectation for the enhanced, interoperable electronic system.

At this point, all DSCSA-regulated trading partners have (or should have) procedures in place to query and document that a trading partner is authorized and must know a trading partner is authorized before entering into a transaction with that entity. The TS the seller provides the buyer in a transaction includes an attestation of being an authorized trading partner. Consequently, we believe it would be redundant, and complicate an already very complex system, to burden it with authorized trading partner status queries to a database that would need to be created and updated very frequently.

[16] We note also that the discussion above regarding "reporting" changes to a product's "status" would also raise data access concerns. As there is no requirement in the DSCSA to report such data, there is similarly no provision regarding who would be entitled to access such potentially highly sensitive information even if it did exist in a centralized database or other format.

IV. RECOMMENDATIONS FOR THE DECEMBER 5-6 PUBLIC MEETING

For the December 5-6 public meeting, HDA strongly urges focus upon identifying the necessary elements for compliance with the DSCSA's 2023 data exchange requirements between trading partners. We believe time and resources should center upon what must be done to meet the statutory requirements and what is workable. We support the discussion of electronic interoperability, with attention first to developing consensus of what interoperability is and what an interoperable system must do to comply with 2023 requirements.

With alignment on what the system must do, we agree that discussion of data architecture and standards will logically follow. We anticipate a robust discussion of aggregation and inference, and urge consideration of which parts of the supply chain are likely to need to aggregate data and the impacts to the supply chain with, and without, aggregation and inference. We suggest that FDA circulate discussion topics, consistent with these recommendations, in advance for feedback.

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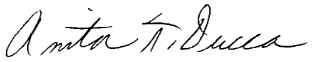
HDA thanks FDA for this opportunity to comments and suggestions on FDA's notice regarding "Enhanced Drug Distribution Security under the Drug Supply Chain Security Act." If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,



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