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RE: Draft Guidance for Industry: Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act, Dkt. No. FDA-2020-D-2024, 86 Fed. Reg. 30053 (June 4, 2021)

Dear Doctor Jung:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments regarding the Draft Guidance for Industry, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act, Dkt. No. FDA-2020-D-2024, 86 Fed. Reg. 30053 (June 4, 2021) (EDDS Draft Guidance or Draft Guidance). We believe there are discrete parts of the Draft Guidance that will be helpful to the pharmaceutical supply chain's collective efforts to implement the requirements of the Drug Supply Chain Security Act (DSCSA) by the statute's November 27, 2023, deadline. We appreciate the agency's efforts in this regard.

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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.

Given the length of our comments, we set forth below a table of contents.

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1. Introduction.

As discussed in detail below, we have serious concerns regarding many parts of the EDDS Draft Guidance. We believe the Draft Guidance (i) does not clearly articulate the essential requirements for 2023 compliance, (ii) is inconsistent (in many respects) with the requirements set forth in the DSCSA, and (iii) is inconsistent (in other respects) with compliance characteristics that the supply chain has been implementing for years and has shared with the agency on numerous occasions, both in meetings and in written comments. Instead, for the first time in guidance, FDA describes a "system" that, we believe, is fundamentally counter to the plain language of the DSCSA and, as such, is not what industry has collectively spent the last seven years investing in and building. Indeed, there is an immense gap between what the Draft Guidance seems to assume industry is implementing and what industry is actually doing.

Given the enormity and complexity of DSCSA implementation, HDA and other stakeholders have frequently explained to the agency what was being done to prepare for 2023 requirements, including how trading partners intended to interoperably exchange transaction data and trace products at the package level. In comments and at public meetings, industry has also noted the difficulties and delays that would arise if FDA's "vision" differed significantly from the compliance solutions trading partners had described, invested in, and were implementing. Unfortunately, this has now occurred, with the Draft Guidance seeming to set out a vision for a "system" that no one is building because no one in the supply chain viewed the DSCSA as requiring it. ***The "system" the Draft Guidance envisions does not exist, is not required by the statute, and, in our considered judgement, cannot be built in time to meet the 2023 deadlines even if it were statutorily mandated.***

HDA greatly appreciates the extension of the comment period.[1] Even with the 30-day extension, however, the comment period is very short for so critically important of a guidance. We have, therefore, focused our comments on the most critical issues and high-level observations. We will continue our review after the close of the comment period and may submit additional comments.

As you will see in the comments below, in many instances, we could not determine precisely what the agency expected and whether that expectation was consistent with the law or achievable from an operational and technical standpoint. As a consequence, it is possible that we have taken a "worst-case" interpretation of certain elements of the Draft Guidance and that FDA did not, in fact,

[1] 86 Fed. Reg. 41853 (August 3, 2021).

intend the particular interpretation we discerned. This, however, is part of the difficulty the Draft Guidance poses for trading partners. If stakeholders must debate for hours, as we have, what the Draft Guidance means, and ***still*** not reach consensus on its meaning, and what trading partners are expected to do, this is an enormous obstacle to industry-wide DSCSA implementation, and, in addition, creates unnecessary enforcement-related anxiety. Without a clear articulation of what is expected and required for compliance, trading partners cannot work cooperatively to achieve the interoperable electronic tracing of products at the package level that the DSCSA requires.

Given the confusion and uncertainty the Draft Guidance has engendered, and because it includes many provisions that we believe are not supported by the law and makes recommendations that cannot be implemented by 2023, ***we respectfully request that the Draft Guidance be withdrawn in its entirety.*** We do not reach this conclusion nor make this request lightly.

HDA fully recognizes and appreciates FDA's acknowledgement that the guidance is not intended to establish "requirements" but rather provides "recommendations."[2] Despite this qualification, and as explained further in Section 4.e, HDA requests withdrawal of the Draft Guidance for many reasons, including: (i) many of the recommendations in the Draft Guidance are inconsistent with the DSCSA; (ii) the lack of clarity regarding some of the recommendations would frustrate and undermine efforts to achieve the standardization that is essential for interoperability and compliance, even if the recommendations were consistent with DSCSA mandates; (iii) many of the recommendations in the Draft Guidance are inconsistent with long-standing industry efforts to build DSCSA-compliant systems (as have been shared with the agency for years); (iv) some recommendations may violate, or require actions that violate, other legal requirements and obligations (*e.g.,* contractual obligations, antitrust laws, other provisions of the Federal Food, Drug and Cosmetic Act (FDC Act), the U.S. Constitution, etc.); and (v) state and federal regulatory authorities often treat -- in enforcement actions, inspections, and licensing decisions -- FDA guidances as imposing requirements.

Not following FDA's DSCSA "recommendations" could have ***serious, real-world and very costly consequences*** for trading partners. A few examples include the following:

- We are aware of reports that reviewers in FDA drug review branches and offices refuse to approve drug labels unless trading partners add the NDC to the human readable interpretation of the 2-dimensional (2D) data matrix barcode as "recommended" in the Product Identifiers Under the Drug Supply Chain Security Act - Questions and Answers Guidance, finalized in June. We understand the FDA reviewers are also insisting upon changes to the presentation of expiration dating in labeling based upon these same "recommendations."

[2] As stated in lines 32 – 35 of the Draft Guidance, "This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, ***should be viewed only as recommendations***, unless specific regulatory or statutory requirements are cited." (emphasis supplied). We note, however, that the Draft Guidance also contains more compulsory language, stating that it "clarifies the enhanced system requirements and describes recommendations for the system attributes ***necessary*** for enhanced product tracing and enhanced verification…" Draft Guidance at lines 62-64 (emphasis supplied).

- The 2018 Draft Guidance for Industry: Standardization of Data and Documentation Practices for Product Tracing, has caused innumerable difficulties in the State of Florida. Florida regulators have interpreted the "recommendations" in that Draft Guidance at lines 310-332 as requiring trading partners to provide the address of the "shipped from" and "shipped to" locations when the DSCSA plainly requires "the business name and address of the person from whom ownership is being transferred" and "the business name and address of the person to whom ownership is being transferred." § 581(26)(I), (J).[3,4]

- In a similar vein, we could easily see a trading partner's facility that is not linked to the Draft Guidance's envisioned "enhanced system" failing a pre-approval inspection[5] or a National Association of Boards of Pharmacy Drug Distributor Accreditation.

Going forward, we urge FDA to focus solely on communicating the specific, DSCSA-stipulated requirements for 2023 interoperability and compliance.

In the sections below, we discuss the following:

- The Draft Guidance appears to describe a "system" that is not what industry has been building (and describing to FDA) for the last seven years to comply with the DSCSA's requirements. We, therefore, provide a detailed description of what industry ***is*** doing to achieve the package level interoperability that the DSCSA requires in 2023. We explain how trading partners intend to interoperably exchange Transaction Information (TI) and the Transaction Statement (TS) in DSCSA-covered transactions. We further explain how wholesale distributors intend to achieve the interoperable tracing of product at the package level given how TI and TS will be provided, received, and maintained.

- The "enhanced system" the Draft Guidance appears to describe does not exist, is not possible to build by 2023, and poses unacceptable security and compliance risks.

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[3] We note that this failure to recognize the DSCSA's preemption of contrary and inconsistent state product tracing requirements as set forth in § 585(a) might have been resolved with the timely release of the state licensure regulations. Now, trading partners are regularly in disputes with state licensure authorities over matters that should be nationally uniform under the DSCSA but are instead subject to different state interpretations and inconsistent requirements. State licensure decisions and related practices remain in the pre-DSCSA patchwork the statute was intended to end.

[4] HDA noted this discrepancy between the Draft Guidance Regarding Standardization of Data and Documentation Practices for Product Tracing's recommendation and the DSCSA requirement for providing the ownership information in its comments filed April 30, 2018. The HDA comments are available here.

[5] A pre-approval inspection is performed to contribute to FDA's assurance that a manufacturing establishment named in a drug application is capable of manufacturing a drug, and that submitted data are accurate and complete. *See, e.g.*, Compliance Policy Guide 7346.832.

- Most importantly, the "enhanced system" contemplated by the Draft Guidance is not what Congress enacted in the DSCSA. It is also contrary to and, indeed, unprecedented, in federal law.

- The Draft Guidance fails to consider critical statutory language on tracing in § 582(g)(1)(D) and (E), leading to an interpretation of tracing requests and responses that we believe is contrary to the plain language of the DSCSA and not legally defensible.

- We highlight particular areas of concern with the Draft Guidance, including,
  - Aggregation and inference;
  - Reconciliation and discrepancies;
  - Verification;
  - Validation;
  - Integration;
  - Alerts; and,
  - Other points.

2. What industry *is* doing to achieve interoperability.

The Draft Guidance "clarifies the enhanced system requirements and describes the system attributes necessary for enhanced product tracing and enhanced verification" for compliance with 2023 requirements.[6] The enhanced system the Draft Guidance describes differs enormously from the systems and processes that pharmaceutical supply chain trading partners have been cooperatively working on and investing in over the last seven years – systems and processes that comply with the DSCSA, have been explained to the agency many times throughout, and which the agency has never voiced any objection to. The enormous gap between FDA's apparent expectations and the reality of what the supply chain has been building cannot be bridged by November 27, 2023, even if required by the DSCSA. For these reasons, it is useful to describe what wholesale distributors ***are*** working on with their trading partners to enable compliance with the DSCSA's 2023 requirements for interoperable transaction data exchange and tracing at the package level.

HDA has explained, since at least 2016, how wholesale distributors were working with their manufacturer and repackager suppliers and dispenser customers to achieve a compliant, enhanced, interoperable electronic system by 2023. Our comments submitted on November 14, 2016, to Dkt. No. FDA-2016-N-2673 are available here, our comments submitted on September 22, 2017, to Dkt. No. FDA-2017-N-3857 are available here, and our comments submitted on June 21, 2021, to Dkt. No. FDA-2020-N-1862 are available here. Another articulation of HDA's views on 2023 interoperability is presented in our Enhanced Drug Distribution Security Traceability in 2023 and Beyond Position Statement.[7]

[6] Draft Guidance at lines 62-63.
[7] Sept. 29, 2020.

a. Interoperability builds upon a foundation of enhanced security.

The DSCSA builds layers of protection over its ten-year implementation that are significantly more protective than the current state, and far more protective than what existed prior to the DSCSA's enactment. Reiterating several of our previous points, essential pillars of enhanced supply chain security (some already in effect, and others becoming effective in 2023) include (but are not limited to):

- Trading partners must be "authorized," and, since January 1, 2015, each trading partner may only engage in transactions of DSCSA-covered products with other authorized trading partners.[8] Also, trading partners ***must*** be authorized in order to initiate and receive responses to verification and tracing requests.[9]

- Product identifiers that conform to the standards of international standards setting organization must be affixed to all covered products, and homogeneous cases of such products, packaged by manufacturers and repackagers after November 27, 2018.[10]

- Trading partners have been providing, receiving and maintaining TI, TS, and Transaction History (TH), as applicable, since 2015 (manufacturers, repackagers and wholesale distributors) and 2016 (dispensers).

- A wholesale distributor must provide a direct purchase statement, when applicable, which serves as an attestation that it purchased directly from a manufacturer, from the manufacturer's exclusive distributor, or from a repackager that purchased directly from the manufacturer.[11] The direct purchase statement provides added assurances of product safety and integrity.

- As of January 1, 2015, and continuing onward to 2023 and beyond, trading partners must have systems and processes in place designed to prevent suspect and illegitimate products from entering the legitimate U.S. pharmaceutical supply chain.[12]

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[8] *See* §§ 582(b)(3), (c)(3), (d)(3), (e)(3) (requirements to transact only with authorized trading partners as of January 1, 2015).
[9] § 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).
[10] 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). *See also Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy, Final Guidance for Industry* (September 2018) available here.
[11] § 582(c)(1)(A)((ii)(I)(aa)(AA). The requirements regarding direct purchase statements have been in place since January 1, 2015, though FDA granted a period of enforcement discretion.
[12] §§ 582(b)(4), (c)(4), (d)(4), (e)(4).

- Since November 27, 2017, manufacturers have had to be able to verify the product identifier on serialized products; this requirement has been in place for repackagers since November 27, 2018.[13]

The requirement for interoperable exchange of TI and TS and tracing in 2023 builds upon these other protections.

b. Interoperable exchange of product tracing data is achieved through the adoption of common standards, including EPCIS and product identifiers.

Sections 582(g)(1)(A) and (B) of the Federal Food, Drug and Cosmetic Act (FDC Act or Act) set out requirements for the interoperable exchange of product tracing data in 2023:

> (A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.
>
> (B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

How wholesale distributors intend to comply with § 582(g)(1)(A) and (B) has been set forth in various comments (here, here, and here, among others) and in HDA's Enhanced Drug Distribution Security Traceability in 2023 and Beyond Position Statement. In brief:

- TI and TS (and the direct purchase statement, if applicable) 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."[14] Currently, EPCIS is the only internationally recognized standard that will meet DSCSA requirements[15] for the interoperable electronic exchange of TI and TS and support the inclusion of product identifiers. These transaction data are confidentially exchanged between a selling and a buying trading partner and remain the private, proprietary records of the respective selling and buying trading partners. At present, there is general consensus across the supply chain that trading partners intend to use EPCIS[16] to meet the DSCSA's interoperability requirement.

[13] § 582(b)(4)(C) (manufacturers), § 582(e)(4)(C) (repackagers).
[14] § 583(h)(4)(A)(i).
[15] *See, e.g.*, § 581(14); § 582(a)(2)(A); § 582(h)(4)(A)(i).
[16] Electronic Product Code Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

- The adoption and use of this common standard for the exchange of product tracing information, including product identifiers for the products transacted, between two trading partners, satisfies the requirement of § 582(g)(1)(A) for the secure, interoperable exchange of TI and TS.

We had hoped that the agency would use the opportunity of the Draft Guidance to endorse EPCIS and acknowledge this international standard as satisfying the DSCSA's 2023 statutory requirements. The 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, recognized EPCIS as a compliant method for meeting the initial DSCSA requirements for interoperable exchange of data. Though still an immature technology for the pharmaceutical and healthcare industries, DSCSA stakeholders have widely adopted EPCIS or are in the process of adopting it. When fully implemented, EPCIS is expected to provide seamless, stable, consistent, compatible, interoperable, electronic connections between trading partners throughout the pharmaceutical supply chain.

c. What industry *is* doing to achieve interoperable tracing at the package level.

How wholesale distributors intend to achieve interoperable tracing at the package level has also been set forth in the same comments cited above (here, here, and here) and in HDA's Enhanced Drug Distribution Security Traceability in 2023 and Beyond Position Statement. In brief:

- Beginning November 27, 2023, when transferring ownership of a product, each authorized trading partner must provide product tracing data – TI that includes the unique product identifier for ***each unit*** in the transaction and TS – to its customers.[17] The customer, in turn, will provide its own TI and TS to its subsequent customer. In each instance, ***TI will reflect the current ownership and sale*** and the product identifiers of the units transacted.[18]

- Direct trading partners will exchange TI and TS using systems and processes that utilize EPCIS, a "form and format developed by a widely recognized international standards development organization."[19] The use of this common standard for the exchange of product tracing data results in legally compliant, unit-level and interoperable traceability between direct trading partners.

- For every transaction of a covered product, a trading partner will have, and be able to provide, in response to an appropriate tracing request, the TI and TS or other information ***in its possession***. A trading partner will be able to identify the transaction in which it acquired the product, and, if it transferred ownership of the product, the transaction where it did so.

[17] § 582(g)(1)(A) and (B).
[18] § 582(g)(1)(A). Transaction history (TH) will not be exchanged between trading partners as of November 27, 2023 as this requirement sunsets and has "no force or effect" as of that date. § 582(k)(1).
[19] § 582(h)(4)(A)(i). *See also* § 581(14); § 582(a)(2)(A).

- Each authorized trading partner holds,[20] owns, and controls the transaction data it provides and receives. As briefly noted above, the DSCSA recognizes the confidentiality of transaction data and permits or requires a trading partner to protect those data from disclosure.[21] A trading partner does not control or otherwise have unfettered access or visibility to the data of other trading partners except to the extent it received those data from a trading partner or passed those data to a trading partner as part of a transaction between the companies.

- As technology and capabilities evolve over time, this process may, ***eventually,*** become more automated, assuming controls can be put in place to assure the security of transaction data and credentialing of requesters. Such technology and capabilities, however, are very complex and do not exist at this time. Important steps toward making this process more automated include the development of a product tracing messaging standard. This would likely be a GS1 technical standard that would implement and support a machine-readable request and response between two authorized trading partners. Further automation will require years of additional work and should ***not*** be incorporated into guidance at this time.

3. The enhanced system described in the Draft Guidance does not exist, cannot be built by 2023, and poses unacceptable security and compliance risks.

The Draft Guidance describes the enhanced system model as "distributed" or "semi-distributed," where a trading partner controls access to its own transaction data.[22] However, elsewhere, the Draft Guidance appears to expect something much different, with FDA, Federal and State officials, and trading partners all having ready visibility into a trading partner's proprietary transaction data through an apparent "system-to-system" interface:

> FDA envisions that the enhanced system will enable appropriate requestors to view product tracing information from all trading partners involved in transactions related to a specific product when requesting the information as part of an investigation of suspect or illegitimate product or a recall. Trading partners' individual systems and processes should be able to collect the relevant transaction information and transaction statement, as applicable, in a rapid, electronic manner from all trading partners that were involved in a transaction for a product being investigated. FDA would expect that Federal or State officials would be able to initiate a single, targeted request for information to trading partners via the enhanced system.[23]

The Draft Guidance goes even further and suggests that FDA and Federal and State officials should have direct access to every pharmaceutical supply chain partner's DSCSA data and proprietary system:

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[20] It is assumed that arrangements with third parties to capture and/or maintain the required data are acceptable, as long as such arrangements recognize that the trading partner employing such a service remains ultimate responsibility for the data and for meeting DSCSA requirements.
[21] The confidentiality provisions of the DSCSA are discussed in detail in Section 4.c. below.
[22] *See, e.g.*, Draft Guidance at lines 219-223.
[23] Draft Guidance at lines 432-439.

> The enhanced system should allow FDA and other Federal and State officials to communicate with trading partners' individual systems and receive relevant information upon request.[24]

While the agency states in lines 444-445 that trading partners should respond to requests for transaction data within one business day, lines 200-202 above suggest the agency expects a system-to-system, automated response. Thus, the Draft Guidance seems to assume that all government authorities and trading partners are networked or connected in some unspecified way, that all transaction data held in the supply chain can be queried in a single request, that the system can return an automated response to that request, and that this enhanced system enables system-to-system, bi-directional connections and communications.

We are not aware of any previous instance in which FDA has expressly articulated such an expectation – particularly as this expectation is contrary to the distributed system that trading partners have been discussing with FDA and other stakeholders and building for many years, and that they have intended to implement in 2023. We discuss in Section 4 that we do not believe a network connecting every trading partner in the pharmaceutical supply chain is at all what Congress enacted in the DSCSA. However, even if the DSCSA provided for, and granted FDA the authority to impose such a far-reaching and unprecedented system upon the pharmaceutical supply chain, additional problems remain.

a. What the Draft Guidance envisions does not exist and cannot be built in time.

While the Draft Guidance tries to characterize the envisioned "enhanced system" as distributed or semi-distributed, elsewhere, the Draft Guidance describes attributes or functionalities that could only exist in a centralized system that every trading partner must subscribe to and participate in, and/or some type of network or global overlay that connects all the systems of every pharmaceutical trading partner.

To accomplish the visibility into all of a product's transactions that lines 432-439 and 200-202 of the Draft Guidance describe, all transaction data generated in the pharmaceutical supply chain would likely have to be uploaded to a single database. Alternatively, there would have to be a connection or overlay that links all trading partners' proprietary DSCSA databases and that is also linked to all state and federal government officials. Each trading partner in the supply chain would have to make its proprietary confidential transaction data available to other trading partners and government officials via this connection and the data in each repository would have to be organized in a manner where it could be queried. There would also need to be the technological capability to send a query to ***all*** of these databases in a single request. The system would then have to compile a record of any relevant transaction data from each of these databases ***and*** return an electronic (and possibly automated) response to the entity making the query.

No system or network exists with this capability and none is currently being built. What does exist is a collection – an ecosystem – of ***thousands of privately owned and maintained systems that***

[24] Draft Guidance at lines 200-202.

are all different. With each trading partner using EPCIS under a common, international, GS1 standard, these different systems become interoperable in that they are able, in a ***business-to-business***, trading partner-to-trading partner connection, to electronically share standardized data sets, enabling the sending and receiving of TS and TI (with product identifiers) and, which will, in turn, enable traceability.

A trading partner ***only*** has immediate, electronic access to the transaction data it interoperably received and the transaction data it interoperably provided and, upon receipt of an appropriate tracing request, a trading partner will be able ***to query its own system*** to provide to the requester the TI and TS or other information it has,[25] if any, for a specific product identifier. A trading partner can, in an appropriate request pursuant to § 582(g)(1)(E), request information from a trading partner who can, in turn, query its own data and return such response as the statute requires.

The Draft Guidance's "enhanced system" seems to be, in contrast, a network able to communicate with every trading partner in the pharmaceutical supply chain, with the ability to query data in thousands of repositories ***and*** generate and receive a response back. Such a system is ***vastly*** more complex than anything being undertaken among trading partners. There are ***no*** efforts underway to link every privately held and maintained repository of highly confidential DSCSA transaction data to one another. There is no consensus on the architecture of such a system. There is no standards development being undertaken to support such a system. Simply put, the "system" the Draft Guidance describes does not exist and is not being built.

Even if the technology, architecture, and standards could be developed or adapted and deployed to support so enormous of an undertaking, such a system could not possibly be built by 2023. The length of time it takes to simply establish electronic connections and successfully send and receive EPCIS file formats between trading partners to achieve interoperability is one hurdle. We explained in our June 21, 2021 comment[26] that, though EPCIS is interoperable between trading partners, efficient, and compliant, its adoption and implementation are complex. It is typically taking four to ten weeks for a wholesale distributor to establish and stabilize the electronic connection with a single manufacturer supplier – and a wholesale distributor typically has hundreds of manufacturer suppliers. And then, wholesale distributors must begin establishing the connections with dispenser customers in order to be able to provide TI that includes product identifiers.[27]

Given the weeks it is taking for this onboarding between a single, sophisticated wholesale distributor and its trusted and highly motivated manufacturer supplier, we see no way this could be expanded to establish the tens of thousands of stable, secure, authenticated connections that would be a necessary pre-condition to "allow FDA and other Federal and State officials to communicate with

[25] In Section 5 we discuss in more detail the responses to tracing requests pursuant to § 582(g)(1)(D) and (E).
[26] HDA's comment may be viewed here.
[27] We believe that many dispenser customers will rely upon their wholesale distributor or service provider to electronically provide TI data into a portal which the dispenser can access, without the need of establishing the point-to-point electronic connection that EPCIS requires.

trading partners' individual systems and receive relevant information upon request."[28] It would take ***years***.

Additional hurdles exist. For the "system" to be able to formulate the query and return a response, it would be necessary to develop a messaging standard so that this complex, two-way electronic communication would be interoperable across the entire – but non-existent – network. The development of a GS1 messaging standard, alone, conservatively takes a year. As mentioned above, we believe that the development of this messaging standard would be helpful to advance tracing requests and responses.

b. The Verification Router Service (VRS) cannot be repurposed to accommodate transaction data or tracing.

We believe that the VRS is the only network in existence that is remotely similar to what the Draft Guidance seems to expect. An incomplete understanding of the VRS may have led to the assumption that the VRS's functionality can be leveraged into a traceability network across the entire U.S. prescription pharmaceutical supply chain. The VRS is useful and functional for verifications and the experience of creating it has been enormously helpful in informing the work to meet 2023 requirements. However, the VRS does not have the capabilities the Draft Guidance expects of the "enhanced system" and it cannot be used for interoperable tracing or data exchange.

The VRS is a privately maintained and operated (though open source) network built by a small number of trading partners and their service providers to enable verification of saleable returns. The VRS was a wholly voluntary endeavor developed as a business necessity because the volume of saleable returns is so large it would rapidly overwhelm wholesale distributors and manufacturers if a rapid, efficient means of automated verification were not developed.[29]

The goal of the VRS is for a wholesale distributor to be able to scan the identifier on a product and the VRS is able to route that query to a Look-up Directory that sends the query to the appropriate manufacturer's data repository, which then sends a response back to the initiating wholesaler that the product identifier is, or is not, verified, with certain other discrete messages also enabled, *e.g.*, the product identifier is verified but the product is recalled (and should not, therefore, be resold).

The VRS has been successful, albeit currently on a small scale with relatively few trading partners participating. The VRS performs only a very discrete, well-defined function that was very, very complex to develop:

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[28] Draft Guidance at lines 200-202.

[29] The VRS is intended to provide sub-second, electronic, automated, verification responses given the hundreds of thousands of returns wholesale distributors process every business day. However, the participants in the VRS all recognized this is a ***voluntary*** accommodation by manufacturers for business and efficiency reasons and to assure that good product would continue to be sold and made available to patients rather than held up for manual verification. Manufacturers otherwise have 24 hours to respond to a verification request. § 582(b)(4)(C).

- Trading partners worked with GS1 over approximately 12 months just to develop a messaging standard for the sending of a machine-readable verification request and a machine-readable response to that verification request. The actual VRS took ***years*** to develop and deploy.

- The VRS had to be able to accept a scan of a product's identifier information from an authorized requester via an electronic interface or manual entry using a VRS portal.

- The VRS involved developing intelligence so that once a wholesale distributor scanned a product identifier, the VRS would know to which manufacturer the verification request needed to be directed. To accomplish this critical routing function, each manufacturer had to upload its product GTINs to a "Look-up Directory" and, with this information, the VRS was able to match the GTIN in the scanned product identifier to a GTIN in the Look-up Directory and route the verification request to the correct manufacturer. With multiple manufacturers, wholesalers, and service providers, multiple Look-up Directories had to be synchronized in real-time.

- For the VRS to work, each manufacturer had to upload its product identifiers to a repository, with the data organized in such a manner so that it could be queried by a VRS request and return a verification response to the requester.

- The VRS had to provide an electronic record or audit trail capability.

The Draft Guidance seems to expect a vast communications system that links thousands of trading partners and that, in response to a tracing request broadcast across the entire network of the U.S. pharmaceutical supply chain, can generate "relevant information" (Draft Guidance at line 202). In contrast, the VRS enables a limited, succinct verification request and response between one wholesale distributor and one manufacturer in a business-to-business, interoperable exchange. Moreover, the participation in the VRS is very small relative to the entire supply chain, with a few manufacturers and wholesale distributors (though all were invited to participate) and an even smaller number of dispensers. The VRS was not designed to, and cannot, support any tracing capability or function across the entire supply chain.

An additional, and ***significantly*** complicating factor in the VRS development was the necessity of service provider collaboration, and cooperation, while also avoiding potential antitrust exposure. Wholesale distributors and manufacturers ***use a number of different service providers*** and so it was necessary to enable verification requests and responses to go outside one service provider's network to reach the companies on and using another service provider's network. Achieving this cross-network synchronicity, voluntarily, required an unprecedented level of cooperation and took ***years*** to accomplish. The VRS is the ***only*** instance where competing service providers agreed, voluntarily, to network with one another and we see significant hurdles to accomplishing this level of voluntary cooperation again, particularly prior to 2023.

c. The enhanced system seemingly contemplated by FDA would pose unacceptable security and compliance risks.

We have serious concerns with the Draft Guidance's assumption that trading partners will open up their proprietary systems for a direct connection with a government authority or with other trading partners. We do not see wholesale distributors or any other trading partners allowing federal or state government officials or other third parties direct, system-to-system connections to their records of every prescription drug product transaction in the U.S. pharmaceutical supply chain. We certainly question whether allowing third party access to data and systems would be aligned with quality management and good manufacturing practices, though wholesale distributors defer to their manufacturer suppliers for a more in-depth analysis of this aspect of the Draft Guidance. We do not believe allowing a third party to directly access wholesale distributor systems is consistent with good distribution and security practices – even within a wholesale distributor's own operation, access to various systems and data are tightly controlled across the organization.

At a bare minimum, a queried system cannot, and should not, return a response unless the requester first presents electronically an appropriate credential. The Open Credentialing Initiative is working to develop an interoperable credentialing system for authorized trading partners. However, this work is still ongoing and there has been no attempt that we are aware of to establish some sort of credentialing for government entities.

Last, we do not see any regulated company providing information to any government entity without first having the opportunity for counsel to review the request and the information to be provided. The issues are too many and too involved to detail here. We believe the concerns may include, but would not be limited to: protection of confidential information from open access laws and Freedom of Information Act requests; clarity that information is being provided pursuant to or in lieu of compulsory process; criminal and civil risks of inadvertently providing incorrect information; and constitutional rights to due process and against self-incrimination.

In sum, the "enhanced system" the Draft Guidance envisions does not exist and cannot, in our view, be built by November 27, 2023. Until the issuance of the Draft Guidance, the supply chain had assumed that the EPCIS-based systems and processes being developed over the last seven years for interoperable data exchange and tracing between trading partners would satisfy the DSCSA's 2023 requirements and that the agency was satisfied with this work. Trading partners were not building a centralized database, single network, or system of interconnected networks because such complex platforms were understood as being neither expected by the agency nor mandated by the law. At this late date, we do not see how the supply chain could, collectively, move to adopt and implement some alternative to EPCIS – an alternative that does not yet even exist.

If, in fact, the Draft Guidance is describing something more akin to a dedicated email communication or secure dropbox, rather than synchronized, system-to-system, two-way communication between FDA and every trading partner in the U.S. pharmaceutical supply chain, the agency should issue a clarification. Immediate, intensive work with stakeholders on the form and content of tracing requests and responses would be an additional, and useful, undertaking.

We discuss in the next section why we believe the enhanced system the Draft Guidance contemplates is contrary to the DSCSA itself and that FDA has far exceeded its statutory authority.

4. The Draft Guidance's "enhanced system" is contrary to what Congress enacted in the DSCSA, is unprecedented in scope, does not preserve confidentiality as the statute requires, and is in excess of agency authority.

It seems that from the phrase "interoperable, electronic tracing of product at the package level" in § 582(g)(1), the Draft Guidance imagines a single "system" that electronically links all trading partners in the U.S. pharmaceutical supply chain, both to each other and to all Federal and State governmental authorities. In numerous ways, we believe the Draft Guidance far oversteps what Congress enacted in the DSCSA.

a. Congress specified standards for achieving interoperability, not a "system."

In the provisions regarding product identifiers and exchange of transaction data, Congress was explicit that both were to be done in accordance with the standards of an international standards development organization.[30] Section § 581(14) requires product identifiers to "confor[m] to the standards developed by a widely recognized international standards development organization." Pursuant to § 582(h)(4)(A)(i) and (iii), FDA was required to develop and finalize a guidance document that, among other things,

> (i) makes recommendations with respect to the **standards** necessary for adoption in order to support the secure, interoperable electronic data exchange …that comply with a form and format developed by a widely recognized international standards development organization…
> [and]
> (iii) **facilitates** the creation of a uniform process or methodology for product tracing…. (emphasis supplied)

While "interoperable" is not specifically defined in the DSCSA, Congress provided the roadmap for achieving it in the definition of product identifier in § 581 and the requirements for transaction data exchange § 582(h). These sections require supply chain-wide alignment on common standards for product identifiers and data exchange, with the implementation of these common standards across trading partners achieving interoperability. In the absence of any guidance from FDA since 2014,[31] this is precisely what trading partners have done – trading partners read and interpreted § 581 and § 582 and worked with GS1 to develop and implement

[30] § 581(14) (product identifier must conform to international standards); § 581(20) (definition of SNI); § 582(a)(2)(A) (initial standards for interoperable data exchange); § 582(h)(4)(A)(i) (final standards for interoperable data exchange).

[31] The 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, recognized EPCIS as a compliant method for meeting the initial DSCSA requirements for interoperable exchange of data.

standards for the product identifier and for transaction data exchange using EPCIS to achieve the interoperability at the package level mandated in § 582(g)(1).

The "enhanced system," as described in the Draft Guidance, disregards the roadmap to interoperability that Congress plainly set out in § 581 and § 582. The Draft Guidance never articulates or even seems to acknowledge Congress's instruction that interoperability is achieved through the adoption and use of common standards developed by an international standards development organization. Indeed, the Draft Guidance ignores the fundamental DSCSA principle that for anything to be interoperable at all, all participants must have adopted and be using a common standard. The only place where the EDDS Draft Guidance recognizes the statutorily-mandated standards intended to enable interoperability is in footnote 18 where the agency states that, in the context of data security, it will promulgate additional guidance.

Instead of focusing upon the standards for achieving interoperability which Congress mandated and the statute sets out, the Draft Guidance describes an "enhanced system." Yet, § 582 makes no reference to this type of "system" at all. The DSCSA does reference, of course, necessary systems and processes trading partners must have.[32] The law also mentions "system attributes."[33] The only instances where the DSCSA refers to a "system," such as is presented in the Draft Guidance, is in the context of public meetings (§ 582(i)(2)(A)) and the potential necessity of additional authority from Congress to implement it (§ 582(i)(2)(G)). The DSCSA in no way requires, or even mentions, the type of "system" contemplated in the Draft Guidance.

b. The Draft Guidance's contemplated implementation of interoperable tracing at the package level is contrary to what Congress enacted.

In previous statements (including comments submitted in 2016 and 2017 and HDA's Enhanced Drug Distribution Security Traceability in 2023 and Beyond Position Statement) and now in Section 2 above, HDA explained that the DSCSA's 2023 requirements for interoperable tracing are satisfied by each trading partner being able to provide the TI and TS or other information in its possession in response to an appropriate tracing request, with confidentiality protections. This is the capability that trading partners have been building toward to meet 2023 requirements.

While the Draft Guidance supports this distributed or semi-distributed model for tracing requests and responses, it nevertheless also appears to expect functionalities that could only exist in some other, far more complex system. Though we have difficulty discerning what, precisely, the Draft Guidance contemplates, the goal, it seems, is for FDA or a trading partner to be able to initiate a single tracing request for a product identifier via the "system" which will somehow query all systems in the pharmaceutical supply chain, that are somehow all linked or networked, and return all transaction data associated with that product identifier. Or, alternatively, all trading partners have uploaded every pharmaceutical product transaction to a single, centralized database or blockchain(s) that can be queried with a "one-button" request. As discussed, there is no network that links all

[32] *See, e.g.*, § 582(b)(4), (c)(4), (d)(4), (e)(4) (systems and processes around verification, illegitimate product); § 582(g)(1)(C), (D), (E), (F) (2023 verification, tracing and saleable returns).
[33] *See, e.g.*, § 582(h)(3)(A); § 582(i)(2)(B).

private transaction data repositories in the U.S. pharmaceutical supply chain, nor plans to build one. Nor do trading partners have any plan to upload all of their transaction data to a centralized database, blockchain, or network of databases.

These complex tracing models would seem to be the only way to accomplish what the Draft Guidance expects. However, the DSCSA grants no authority to create, manage, or fund any such "system." We believe that supply chain members in foreign countries using central data repositories typically have a governmental entity manage such repositories pursuant to clear legal authority with a defined source of funding to support them. The DSCSA neither mandates the creation of such a system nor provides for this critical development or structure. Stakeholders would have to bear the costs and liabilities to develop, design, build, and manage this "system," and bear the considerable antitrust risks of doing so.

We see additional ways the Draft Guidance's "enhanced system" is contrary to what Congress enacted:

- To the extent the Draft Guidance expects that trading partners will send or post transaction data to a central repository, blockchain, or networked repository in order to achieve its envisioned functionality, the DSCSA contains no such requirement. Every trading partner in the supply chain would have to ***voluntarily*** post or expose all of their transaction data. Without a clear and specific mandate for participation (which could only be accomplished through a statutory amendment), we do not see how the Draft Guidance's system could accomplish tracing across all trading partners in the U.S. pharmaceutical supply chain.

- The Draft Guidance seems to seek, with a single scan, a product's Transaction History (TH) back to the original manufacturer. 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."[34] Nothing in § 582(g)(1) suggests that the trading partner that is responding to a tracing request is responsible for collecting the TI for each transaction going back to the manufacturer (that is, TH). If Congress had intended for a single responder to provide a product's TH back to the manufacturer's first transaction, it would have stated in § 582(g)(1)(D) and/or (E) that the responder had to have "systems and processes to produce the transaction information for each transaction back to the manufacturer." Alternatively, Congress would not have sunsetted TH in § 582(k)(1). In Section 5 below, we discuss further what we believe § 582(g)(1)(D) and (E) require.

- If Congress had intended for a single scan or press of a button to yield every transaction for a product identifier, it had the template for doing so in California's electronic pedigree law, SB 1307. SB 1307 explicitly stated that a product had to have an electronic pedigree, comprised of "information regarding each transaction" from the manufacturer's first sale, onward, all the way to the point of administration or dispensing to the patient and the pedigree had to be

[34] § 582(k)(1).

maintained through all stages of distribution.[35] In contrast, the DSCSA has each trading partner hold and control its own transaction data with, in 2023, no requirement for that data to follow a product through each transaction in the supply chain. This structure exists in part because stakeholders could not see a technologically feasible way of maintaining a single record for a single product that updated as the product moved through the supply chain as SB 1307 required. The DSCSA contains none of the specific language in the California law that gave rise to this "scan-and-see" requirement. The DSCSA preempted SB 1307 and other State traceability laws to establish a uniform national policy for the tracing of pharmaceuticals.[36]

- The DSCSA does mandate the creation of a centralized database in certain, specified circumstances. FDA was required to establish a searchable database of the state licensure information that wholesale distributors and third-party logistics providers must submit to the agency. However, the statute makes no provision at all for the creation of a centralized repository or database for transaction data. When, as here, "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 inclusion or exclusion." *I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987) (internal quotations and citations omitted). *See also AMG Capital Management, LLC. v. FTC,* 141 S.Ct. 1341 (2021) (Congress providing for monetary penalties in one part of the FTC Act but not another meant FTC did not have monetary relief authority in those parts of the FTC Act where it was not identified as a remedy). We do not believe FDA has the authority to interpret the DSCSA in a manner that requires trading partners to provide or post transaction data to a central or networked data repository.

c. The direct system access contemplated by the Draft Guidance is unprecedented.

It appears to us that the Draft Guidance assumes that the word "interoperable" entitles FDA to connect directly to the proprietary computer systems of each pharmaceutical supply chain trading partner – thousands of manufacturers, repackagers, wholesale distributors and dispensers. Moreover, the Draft Guidance appears to assume that, through these direct, system-to-system connections, FDA (and any other appropriate government authority) may initiate a query and pull or receive an automated response from a trading partner's system with a product's complete transaction data – from manufacturer through dispenser. If this is, indeed, what the Draft Guidance interprets the DSCSA to require, we believe it would be without precedent in federal law.

We are not aware of any other similar scheme under federal law that permits the government to initiate a direct connection to the system of regulated industry and to pull information from that private entity's system or to receive an automatic response from the queried system. To our

[35] 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.
[36] § 585(b)(1).

knowledge, even highly regulated entities such as financial institutions do not have direct, system-to-system communications with their regulators.

We believe interpreting the DSCSA to permit FDA to directly connect with and pull transaction data from regulated industry's private, proprietary data systems and processes raises, among other things, serious concerns of lack of notice and due process. Where the DSCSA requires a response from a trading partner, such as to tracing and verification requests, it provides time for the trading partner to respond,[37] thereby respecting the basic notice and process rights of the responding party. If Congress had intended to grant a federal agency the extraordinary power to connect directly to the proprietary data of the thousands of private trading partners in the U.S. pharmaceutical supply chain, it would have surely so stated.

d. The system the Draft Guidance described does not afford confidentiality of the transaction data as the DSCSA mandates.

The Draft Guidance briefly mentions confidentiality of transaction data at lines 236-244 and explains that "FDA expects trading partners to ensure that they will maintain the confidentiality of product tracing information through usual business practices."[38] This language appears most concerned with a trading partner keeping its own transaction data secure, but does not attempt to reconcile the confidentiality protections in the DSCSA with the provision elsewhere in the Draft Guidance that the enhanced system "will enable appropriate requestors to view" the highly confidential and proprietary "product tracing information from all trading partners involved in transactions related to a specific product…"[39] We are quite concerned with this interpretation and find it at odds with the DSCSA's own attention to maintaining the confidentiality of transaction data.

DSCSA-related data, particularly a company's suppliers, customers, and product volumes, are proprietary, highly confidential commercial information and may include or constitute trade secrets. In addition to limiting who may initiate a tracing request and when (*see* Section 5 below and § 582(g)(1)(D) and (E)), the DSCSA protects transaction data in other ways:

- Manufacturers, wholesale distributors, dispensers and repackagers may each develop their own "secure electronic database" to meet the verification requirements of § 582 (or use a secure database operated by a third party).[40]

- Dispensers may have third parties "confidentially maintai[n]" their transaction data.[41]

- Wholesale distributors must "maintain the confidentiality of the [TI, TH, and TS] for a product in a manner that prohibits disclosure to any person other than the [FDA] or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as

[37] *See e.g.*, § 582(m); § 582(b)(4)(C); § 582(e)(4)(C).
[38] Draft Guidance at lines 239-241 (footnote omitted).
[39] Draft Guidance at lines 432-434.
[40] § 582(b)(4)(D); § 582(c)(4)(C); § 582(d)(4)(C); and § 582(e)(4)(D).
[41] § 582(d)((1)(B); § 582(g)(2)(A).

applicable, pursuant to an agreement under subparagraph (D)."[42] Clauses (ii) and (iii) referenced in § 582(c)(1)(A)(v)(II) are the requirements for a wholesale distributor to provide TI and TS in a product transaction to its downstream direct trading partner.

- When a trading partner receives a tracing request from another, authorized, trading partner, the systems and processes for making and responding to a request must be "in a secure manner that ensures the protection of confidential commercial information and trade secrets." § 582(g)(1)(E)(ii).

The Draft Guidance fails to protect a trading partner's confidential transaction data from other trading partners. Nor does the Draft Guidance recognize the serious confidentiality concerns of disclosing a product's transaction data to trading partners who did not generate it or receive it – simply because TI and TS for a product are exchanged between the two trading partners that transacted the product does not mean that the data loses its confidentiality as to any other trading partner that was not a party to the transaction. The section of the Draft Guidance on initiating and responding to tracing requests, Draft Guidance at lines 423-448, makes no reference to maintaining confidentiality at all even though § 582(g)(1)(E)(ii) specifically requires preserving the confidentiality of information a responding trading partner may be asked to provide to another trading partner who initiated a tracing request.

Additionally, the Draft Guidance's interpretation of the DSCSA, as indicated by the statement that "FDA envisions that the enhanced system will enable appropriate requestors to view product tracing information from all trading partners involved in transactions related to a specific product" (at lines 432-434) is inconsistent with the law itself. ***Wholesale distributors are prohibited from providing TI and TS to another trading partner except as part of a transaction with that trading partner or pursuant to an agreement*** (*see* § 582(c)(1)(A)(v)(II)). To the extent the Draft Guidance insists that interoperability means that every trading partner must be able to request and see every other trading partner's transaction data, it ignores the protection of that highly confidential transaction data that the DSCSA expressly mandates.

Under the DSCSA, FDA also must promulgate guidance to protect the confidentiality of transaction data. Sections 582(h)(3)(A)(iii) and 582(h)(4)(A)(iv) require FDA to finalize guidance on unit level tracing and standards for interoperable data exchange that "ensure[s] the protection of confidential commercial information and trade secrets." Footnote 18 of the Draft Guidance indicates FDA intends to issue future guidance on security to support interoperable data exchange as specified by § 582(h)(4)(A), though that footnote appears to be focused upon internal measures that trading partners must take to assure their systems and processes are secure, and not regarding what measures must be in place to protect confidential commercial information and trade secrets potentially sought by other trading partners. The DSCSA requires the protection of confidential commercial information and trade secrets and we urge future guidance to acknowledge and address the protections the statute mandates.

[42] § 582(c)(1)(A)(v)(II).

e. As guidances do not have the force of law, language in the Draft Guidance suggesting otherwise should be eliminated.

At the outset, the Draft Guidance states, as all FDA guidances do, it does "not have the force and effect of law and [is] not meant to bind the public in any way…."[43] The Draft Guidance should be viewed only as "recommendations."[44]

However, the Draft Guidance also states:

> This guidance clarifies the enhanced system requirements and describes recommendations for the system attributes ***necessary*** for enhanced product tracing and enhanced verification, including when the use of aggregation and inference may be appropriate.[45]

It seems, therefore, that while the Draft Guidance is intended to be (and by law, can only be) recommendations,[46] FDA is also stating that following those recommendations is "necessary" to satisfy the legal requirements for enhanced product tracing and verification in 2023. Moreover, the DSCSA specifically requires, when promulgating regulations, that the FDA, among other things, "provide appropriate flexibility" and may "not require[e] the adoption of specific business systems for the maintenance and transmission of data," and must prescribe "alternative methods of compliance."[47] The Draft Guidance, with its recommendations "necessary" to satisfy 2023 requirements, offers none of this requisite flexibility. While the Draft Guidance does not identify any business system by name, the "enhanced system" it describes does not seem attainable unless trading partners participate in a blockchain, centralized database, or shared network.

An additional and ongoing problem is that regardless of the conditional language present in the Draft Guidance, and assertions that a guidance represents only recommendations, regulated industry rightfully takes FDA guidances very seriously. State inspectors, auditors, trading partners, and even other FDA personnel often treat FDA guidances as legally binding (or at least highly authoritative) and any entity that does not follow them is often deemed to be out of compliance. We are especially concerned that state regulatory authorities will delay or deny licensure because wholesale distributors and other trading partners are not participating in the "enhanced system" with the functionalities described in the Draft Guidance – a system that does not exist and which the DSCSA does not require.

In conclusion, the Draft Guidance appears to set out an "enhanced system" far in excess of what the DSCSA requires.[48]

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[43] Draft Guidance at lines 31-32.
[44] Draft Guidance at line 34.
[45] Draft Guidance at lines 62-64 (emphasis supplied).
[46] *See, e.g.*, 21 C.F.R. § 10.115 (FDA Good Guidance Practices Regulation).
[47] *See* § 582(g)(4).
[48] Congress itself recognized that FDA might need additional authority beyond what it granted in the DSCSA. Section 582(i)(2)(G) provides that, at one of the public meetings FDA was required to convene, the agency should consider "The technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level."

5. Section VI. of the Draft Guidance, "Gathering Of Relevant Product Tracing Information," is not aligned with § 582(g)(1)(D) and (E).

Based on industry discussions about and independent of the content of the Draft Guidance, we believe there is persistent confusion surrounding the initiation of, and responses to, requests for tracing information. We believe any difficulties in developing a shared understanding of tracing requests and responses could be minimized or avoided altogether by focusing upon what § 582(g)(1)(D) and (E) actually say and how they relate to other parts of the DSCSA.

The Draft Guidance begins well with the citation to, and paraphrase of, the relevant statutory language at lines 81-92. However, the Draft Guidance makes no further attempt to parse the dense language of (D) and (E) and, in addition, collapses these two, separate and distinct provisions of the DSCSA into a general discussion of "tracing." We believe this results in a presentation of tracing obligations in Section VI, "Gathering Of Relevant Product Tracing Information," that is not aligned with the DSCSA. Lines 432-439 of the Draft Guidance[49] in particular appear to be inconsistent with and contrary to (D) and (E).

Courts have been clear that ignoring statutory text can endanger agency interpretations. Applying traditional tools of statutory interpretation, recent Supreme Court cases have emphasized the importance of closely adhering to the common meaning of a statute's plain language. *See Facebook, Inc. v. Duguid et al.,* 141 S.Ct. 1163, 1170 n. 5 (2021) ("Courts should approach these interpretive problems methodically, using traditional tools of statutory interpretation, in order to confirm their assumptions about the 'common understanding' of words"); *AMG Capital Management, LLC,* 141 S.Ct. at 1347-1348 (Section of FTC Act referring only to "injunction" precluded imposition of monetary penalties; the fact Congress in other parts of the FTC Act provided for monetary penalties leads to the conclusion that FTC does not have monetary relief authority in those parts of the FTC Act where it was not identified as a remedy).[50] *See also The Judge Rotenberg Educational Center, Inc., v.*

[49] "FDA envisions that the enhanced system will enable appropriate requestors to view product tracing information from all trading partners involved in transactions related to a specific product when requesting the information as part of an investigation of suspect or illegitimate product or a recall. Trading partners' individual systems and processes should be able to collect the relevant transaction information and transaction statement, as applicable, in a rapid, electronic manner from all trading partners that were involved in a transaction for a product being investigated. FDA would expect that Federal or State officials would be able to initiate a single, targeted request for information to trading partners via the enhanced system." Draft Guidance at lines 432-439.

[50] We note that these were not contentious decisions of the U.S. Supreme Court. *Facebook, Inc. v. Duguid et al.*, was 9-0, with Justice Alito concurring in the judgement and *AMG Capital Management, LLC, et al. v. Federal Trade Commission* was unanimous. *AMG Capital* is especially noteworthy. The Supreme Court rejected the FTC's 30-year practice of obtaining monetary relief from defrauded consumers in court proceedings – the enormous equities of disgorging ill-gotten gains from fraudsters to cure consumer injury were irrelevant because Congress had specifically only identified the right of the FTC to obtain monetary relief in administrative proceedings. The section of the FTC Act granting the agency the authority to proceed in court mentioned only injunctive relief, leading to the presumptive and unanimous conclusion of the Court that Congress intended for the agency to have monetary relief authority only in administrative, and not judicial, action. There are numerous places in the DSCSA where Congress expressly requires an action, a notification, or other measure and is silent elsewhere, leading to the presumptive conclusion that these inclusions and omissions are deliberate and must be given meaning.

FDA, No. 20-1087 (D.C. Cir. July 6, 2021) (applying common dictionary definitions to words in the FDC Act to conclude FDA had exceeded its authority).

We believe a careful reading of § 582(g)(1)(D) and (E) and application of the established and recently affirmed principles of statutory construction provide a roadmap to tracing requests and responses. We present below what we believe constitutes a compliant framework for tracing requests and responses after November 27, 2023, pursuant to § 582(g)(1)(D) and (E). The "system" that we describe below is what we believe should be incorporated into any agency guidance on this subject.

a. The language of Sections 582(g)(1)(D) and (E).

As the Supreme Court stated in *Facebook, Inc.*, 141 S.Ct. at 1169, "We begin with the text." Section 582(g)(1)(D) and (E)[51] state:

> (g) Enhanced drug distribution security
> (1) In general
> On the date that is 10 years after November 27, 2013, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:
> …
> (D) The systems and processes necessary ***to promptly respond with the transaction information and transaction statement for a product*** upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.
>
> (E) The systems and processes ***necessary to promptly facilitate gathering the information*** necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—
>
> (i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or
>
> (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).[52]

A serious issue in Section VI of the Draft Guidance is that it seems to disregard the fundamentals of statutory construction by collapsing all tracing requests and responses into a few

[51] For simplicity, we will sometimes refer to § 582(g)(1)(D) and (E) as "(D)" and "(E)" respectively, *e.g.*, a "(D) request," an "(E) response."
[52] § 582(g)(1)(D) and (E) (emphasis supplied).

sentences in a single paragraph at lines 432-448. ***Sections (D) and (E) are not the same and the differences are material to an understanding of what they require***. Sections (D) and (E) describe different requests, from different entities, under different circumstances, and different responses. The Draft Guidance mashes them together into a general discussion of "tracing," and blurs the distinctive elements of each. This is not what Congress did, this is not what the DSCSA provides, and any effort to elucidate DSCSA tracing requests and responses must respect and acknowledge these two, distinct and separate, provisions. Congress's desire and direction to give meaning to both (D) and (E), and to respect the differences between the two, is particularly clear considering ***that they follow one right after the other***. Sections (D) and (E) are distinct and together form a comprehensive tracing framework.

b. § 582(g)(1)(D) and (E) limit when a tracing request can be initiated and who may initiate it.

The circumstances under which a trading partner must respond to a request made under § 582(g)(1)(D) and (E) are well-defined and very limited (emphasis supplied):

> (D) – "***upon a request by the Secretary (or other appropriate Federal or State official)*** in the event of ***a recall*** or ***for the purposes of investigating a suspect product or an illegitimate product***…."
>
> (E) –
> clause (i) "in the event of a ***request by the Secretary (or other appropriate Federal or State official)***, ***on account of a recall or for the purposes of investigating a suspect product or an illegitimate product***; or
> clause (ii) "in the event of a ***request by an authorized trading partner*** … ***for purposes of investigating a suspect product*** or ***assisting the Secretary (or other appropriate Federal or State official)*** with a request described in clause (i)" (that is, "***in the event of a recall*** or ***for purposes of investigating a suspect or an illegitimate product***").

The Draft Guidance paraphrases (D) and (E) in a single sentence: "In the event of a recall or for purposes of investigating a suspect product or illegitimate product, section 582(g)(1)(D) and (E) of the FD&C Act requires trading partners to have the systems and processes necessary to promptly respond with the [TI and TS] for a product, and to promptly facilitate the gathering of information necessary to produce the [TI] for each transaction going back to the manufacturer, as applicable, upon request by a Federal or State official or (in the case of section 582(g)(1)(E)) authorized trading partner."[53]

The Draft Guidance does not, therefore, break down the prerequisites for tracing requests under (D) and (E) at all. It does not address that under (D), ***only*** the Secretary, that is, FDA, or other appropriate Federal or State official, may request a product's TI and TS and may do so ***only*** in the event of a recall or for purposes of investigating a suspect product or an illegitimate product. Nor does it clarify that under clause (ii) of § 582(g)(1)(E), an authorized trading partner must be acting on

[53] Draft Guidance at lines 423-429.

behalf of a government authority to request other information from another authorized trading partner on account of a recall or for the purposes of investigating a suspect product or an illegitimate product.

There is one exception in § 582(g)(1)(E)(ii) for trading partner-initiated requests. However, lines 423-429 also do not incorporate this critical, limiting language. Under clause (ii), an authorized trading partner may ***only*** initiate a tracing request ***on its own*** in the event of a suspect product investigation. We are concerned with compliance with this requirement. If trading partners are initiating a tracing request, they must be otherwise complying with the suspect product verification requirements of § 582, including quarantining, investigation, and documentation, and they must have reason to believe the product is suspect under § 581(21).

No other entity, under any other circumstance, may initiate a request for tracing information except as expressly provided for in (D) and (E).

c. (D) and (E) provide for different outputs in response to an appropriate tracing request.

Sections (D) and (E) also ***require different output*** in response to an appropriate request:

(D) –provide "TI and TS" –
> The responder must have "systems and processes necessary to promptly respond with the ***transaction information and transaction statement***…"

(E) – provide "information" –
> The responder must have "systems and processes necessary to promptly facilitate gathering ***the information*** necessary to produce the transaction information going back to the manufacturer…"[54]

An (E) response, therefore, is comprised of "information," ***not TI***. If Congress had intended for an (E) response to be or include TI, it would have said so, as it did in other parts of the DSCSA. Where a trading partner ***is*** required to produce TI (rather than "information"), Congress and the law are very clear.[55] Including language in one place in the DSCSA and not in another is presumed also to be the deliberate decision of Congress.[56]

This difference between production of TI in (D) and production of "information" in (E) must not be ignored. Subsections (D) and (E) must be read together, with meaning given to both sections of

[54] § 582(g)(1)(D) and (E) (emphasis supplied).
[55] *See, e.g.*, 582(g)(1)(D); "Requests for Information" in § 582(m), §§ 582(b)(1)(B) (manufacturer), (c)(1)(C) (wholesale distributors), and (e)(1)(C) (repackagers), requiring provision of TI and TS within 24 hours in 2023.
[56] *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where 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 inclusion or exclusion") (internal quotations and citations omitted); *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).

the law.[57] Interpreting (E) to mandate production of TI in response to requests generated by governmental authorities would render (D) impermissibly meaningless and superfluous[58] – there would be no reason for Congress to have written (D) if governmental authorities could always proceed under (E) to obtain TI. As to requests by trading partners, TI could certainly be highly confidential, for example, if a trading partner is requesting information about a product that the responder did not sell to the requester or purchase from the requester. As discussed below, (E) permits the responder to protect its trade secrets and confidential commercial information by providing "information" rather than confidential TI.

This requirement to provide "information" rather than TI is logical and indeed, for wholesale distributors, is compelled by § 582(c)(1)(A)(v)(II). Under § 582(c)(1)(A)(v)(II), a wholesale distributor responding to a tracing request initiated by a trading partner on its own behalf can ***only*** provide information and cannot provide TI and TS unless either provided for in an agreement or if the wholesale distributor transacted the product subject to the request to that requesting trading partner.[59] In light of this flat prohibition in § 582(c)(1)(A)(v)(II)), can ***only*** provide information.

The Draft Guidance does not address these different outputs that (D) and (E) require. The Draft Guidance simply states that "Trading partners' individual systems and processes should be able to collect the relevant transaction information and transaction statement, as applicable, in a rapid, electronic manner from all trading partners that were involved in a transaction for a product being investigated."[60] Applying traditional principles of statutory interpretation and canons of construction, which the Supreme Court so recently used and reaffirmed, it must be presumed that Congress acted intentionally in creating (D) and (E) and that meaning must be given to both provisions. The Draft Guidance impermissibly eliminates these crucial differences in tracing output that Congress enacted in (D) and (E).[61]

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[57] *See e.g.*, *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973).
[58] *Weinberger*, 412 U.S. at 633. *See also Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant...." (internal citations and quotations omitted).
[59] A wholesale distributor shall "maintain the confidentiality of the [TI] (including any lot level information consistent with the requirements of this section), [TH, and TS] for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D)." § 582(c)(1)(A)(v)(II).
[60] Draft Guidance at lines 435-437. *See also* Draft Guidance at lines 440-443 ("Assuming a distributed or semi-distributed data architecture model, in the enhanced system, trading partners would receive a request and respond with relevant transaction information if they were involved in an transaction associated with the products that are subject to the request.")
[61] We note also that the express language of (E) undermines any support for a "one-button" tracing system which the Draft Guidance seems to expect. As discussed, (E) provides that trading partners must have "systems and processes necessary to promptly facilitate gathering the information necessary to produce the [TI] going back to the manufacturer." If all TI was available with a single scan or push of a button, there would be no reason for gathering information to produce TI back to the manufacturer because it would all be available immediately.

d. "Information" provided in response to an (E) request.

Section 582(g)(1)(E) requires the trading partner to have systems and processes to promptly facilitate gathering "the information" necessary to produce the TI going back to the manufacturer. Contrary to what the Draft Guidance states, *e.g.,* at lines 432-435, ***the responding entity is expressly not required to provide TI and is not required to provide TI going all the way back to the manufacturer***. Rather, the responder is providing information so the requester can gather the TI back to the manufacturer.

As to what information the responder will provide in response to an appropriate (E) request, the output will likely vary depending upon the entity that is initiating the request. Where the requester is another authorized trading partner, rather than a governmental entity, (E)(ii) ensures protection of the responder's confidential commercial information and trade secrets.[62] For wholesale distributors, this is an important protection as § 582(c)(1)(A)(v)(II) prohibits a wholesale distributor from providing TI and TS to anyone except a government official, the direct trading partner with which they transacted the product, or as otherwise provided for by agreement.

A government requester would (and should) obtain TI and TS from a trading partner pursuant to a request made under § 582(g)(1)(D); consequently, information provided in response to an (E) request would involve the government's need for information apart from transaction data. Like any production to the government, legal and regulatory counsel may be involved and the scope of any response discussed with the FDA or other requesting governmental authority.

6. Other specific sections of the Draft Guidance are unclear, are contrary to the DSCSA or are far in excess of FDA's statutory authority, and/or are not operationally possible.

We address specific concerns with the Draft Guidance below. Although we urge FDA to withdraw the Draft Guidance completely, should the agency elect not to do so, we offer suggested language and editorial changes that might inform future revisions (with suggested changes in **blue bold** and ~~red strikeout~~).

a. Aggregation and inference, Section III.B. of the Draft Guidance.

We appreciate FDA affirmatively stating that aggregation and inference are critical elements of a secure and efficient supply chain. Without aggregation and inference, it would become necessary to open sealed containers to scan the items within the container to incorporate the product identifiers for units within the sealed container in the TI for the shipment. Such an undertaking would create massive operational problems for manufacturers and wholesale distributors who do not have room in their shipping operations to open every case, remove each product within them, and scan them. All trading partners (manufacturers, distributors, and dispensers) rely upon aggregation and inference and the Draft Guidance's recognition of the concept is very helpful.

[62] Any response to a tracing request made under § 582(g)(1)(E)(ii) shall be "in a secure manner that ensures the protection of confidential commercial information and trade secrets."

However, we do have concerns with aspects of Section III.B. First, we note that FDA uses the term "data aggregation" (Draft Guidance at line 125) and provides examples of the concept.[63] We find the term confusing as it suggests other types of aggregation that might, or might not, be within the scope of the Draft Guidance. We suggest deleting the term "data aggregation" and replacing it with "aggregation."

There are several instances where the Draft Guidance suggests that a selling trading partner does not need to include all the identifiers for products sold in a transaction if the selling trading partner provides aggregated data. We found these mentions confusing and inconsistent with the DSCSA which requires, beginning November 27, 2023, that TI "shall include the product identifier at the package level for each package included in the transaction."[64] The Draft Guidance later also emphasizes that TI must include the product identifier for each package.[65] Therefore, the selling trading partner should provide the product identifiers in TI. The Draft Guidance should not suggest that trading partners may avoid sending product identifiers in TI.

We suggest the following changes to make these points clearer:

Lines 133-136: "Multiple homogeneous cases of product on a pallet: A data file that reflects the contents of the pallet, including the individual, unique product identifiers associated with each homogeneous case and~~/or~~ with packages within the case provided by the selling trading partner to the purchasing trading partner.

Lines 138-149: A selling trading partner and its purchasing trading partner(s) should decide how they will share data file(s) in a secure, efficient manner that allows the purchasing trading partner(s) to use the data file for determining the information that is associated with each package of product. ~~For example,~~ **A** selling trading partner may choose to (1): send the data file in its entirety to the purchasing trading partner(s), which lists all product identifiers of each package of product contained in a sold homogeneous case**; or (2) send TI which includes product identifiers of each package of product in a sold homogenous case to a portal that the purchasing trading partner can access**~~; or (2) provide the product identifier associated with the homogeneous case to the purchasing trading partner(s), who could use the product identifier to look up and access the data file containing individual product identifiers for each package of product in that case. The scenario described in example (2) could involve reading the product identifier in the linear or two-dimensional (2D) data matrix barcode for the homogeneous case to retrieve the individual product identifiers for each package of product that should be physically in the case~~.

We are also very concerned with lines 174-179 to the extent they suggest that inference may only be used for homogenous cases. Trading partners frequently sell and receive non-homogenous cases and "mixed totes" – most dispensers receive products from their wholesale distributors in this

[63] Draft Guidance at lines 125-136.
[64] § 582(g)(1)(B).
[65] Draft Guidance at lines 266-268.

format rather than a single homogenous case. Wholesale distributors intend to continue this established practice post-2023 by assigning a number to a case or tote that contains non-homogenous or mixed products and then aggregating the individual units to the assigned case or tote identifier. Lines 174-179 suggest that a "trading partner should only use inference when it receives pallets ***or homogeneous cases*** …" and that "Receiving a pallet ***or homogeneous case***" with broken tape or wrap means the trading partner should not use aggregated data until it determines the product is not suspect. We urge deleting the term "homogenous" in these lines to assure that trading partners will be able to use aggregation and inference for mixed and non-homogenous cases, totes, and other containers.

b. Reconciliation and discrepancies, Section V.B., C., and D. of the Draft Guidance.

We have numerous concerns with the Draft Guidance's reconciliation provisions. We believe that the concepts described in this part of the Draft Guidance are new, having never been discussed or raised with industry previously. They are not reflective of operational reality and, to implement them, would require massive changes to operations, including the dedication of tens of thousands of square feet of additional warehouse space; we believe that implementation of these recommendations would also be likely to severely impact our ability to efficiently provide timely delivery of medicines to patients.

Lines 292-302 state:

> With electronic product tracing information and product identifier information (in the 2D data matrix barcode for packages of product and in the linear or 2D data matrix barcode for homogeneous cases of product), selling trading partners should develop and use processes that automate the recording of the electronic data in the transaction information and transaction statement associated with the product physically shipped to the purchasing trading partner. This could be accomplished by the selling trading partner reading the 2D data matrix barcode on the packages of product to fulfill a customer's order and including that information in the product tracing information sent to the purchasing trading partner. If the transaction involves sealed homogeneous cases of product, a selling trading partner may provide transaction information listing the product identifiers for the cases that links to the aggregated package product identifiers in each case.

We generally agree with this part of the Draft Guidance though, as discussed in the section above, it is not optional under the DSCSA for the selling trading partner to provide identifiers in TI for each product in a transaction. We recommend revision to assure this statutory duty is clear.

However, lines 302-306 cannot be reconciled with the Draft Guidance's previous discussion of the acceptability of aggregation and inference:

> The product tracing information that will be provided to the purchasing trading partner in an electronic format should be checked to ensure that it accurately reflects the product that will be physically shipped. This step helps to ensure that the product that is physically packed into a

> shipping unit is properly associated with the data that is provided to the purchasing trading partner.

This step cannot be accomplished if trading partners are transacting in sealed cases and totes as it suggests that every package the purchasing trading partner receives must be "checked," that is, removed from the larger container, and scanned in order to be "properly associated" with the data received from the selling trading partner. The provisions on aggregation and inference in Section III.B. of the Draft Guidance specifically state that the contents of sealed cases may be inferred and that they do not have to be (and, for security and operational reasons should not be) opened.[66] We suggest deleting lines 302-306.

We have serious concerns regarding lines 329-344 as they suggest that a purchasing trading partner could be out of compliance with the DSCSA if it did not "undertake reconciliation upon physical receipt of the product and then before selling the product to help confirm the veracity of the inbound and outbound transactions."[67] The Draft Guidance also states:

> Reconciliation would involve checking that the product tracing information received in an electronic format accurately reflects the packages of product the purchasing trading partner physically received. Reconciliation could be accomplished by physically checking the product identifiers of each package against associated electronic transaction information or physically checking the product identifiers of sealed, homogeneous cases of product against associated electronic transaction information.[68]

If the Draft Guidance expects, regardless of use of aggregation and inference, that all sealed inbound containers (cases, pallets, etc.) be opened and the contents within them reconciled to data received, such an effort is virtually impossible from an operational perspective. To generate outbound TI for products they sell, wholesale distributors do intend to scan individual package identifiers both to confirm they received transaction data for that package and to generate outbound TI populated with the package's product identifier. If selling a homogenous case, wholesale distributors intend to scan the case identifiers and confirm that they received aggregated data on both the sealed case and the individual packages within the sealed case and will use the aggregated data received for that sealed and aggregated case to generate outbound TI when selling the homogenous case.[69]

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[66] In fact, the Draft Guidance specifies that the contents of a case should not be inferred if the security seals are broken. Broken seals may be an indicator of a suspect product. Draft Guidance at lines 174-178.

[67] Draft Guidance at lines 329-331.

[68] Draft Guidance at lines 331-337. *See also* lines 339-342: "The purchasing trading partner can use the product identifier to automate the receipt of the shipment by reading the barcode(s) and entering the information into its individual system, in addition to checking this information against the electronic product tracing information that the purchasing trading partner received."

[69] In the instance of non-homogenous cases, such as totes, these are expected to be totes that the wholesale distributor assembles for a dispenser customer and the wholesale distributor would scan the eaches placed in the tote prior to shipment and sale. This outbound scan would assure that the wholesale distributor received product identifier data for each of the products in the non-homogenous tote. The "eaches" would be aggregated to a case/tote identifier the wholesale distributor assigns.

To go beyond these intended business processes, and require a check at receiving of *each* unit within a larger container cannot be done given current operations and while maintaining the efficiencies that are necessary to ensure timely distribution of drugs. To operationalize this part of the Draft Guidance, we believe it would require wholesale distributors to break up pallets and cases received in sealed trucks as regular, routine scheduled shipments from longstanding, established authorized trading partners.

The number of cases received by individual wholesale distributors, and individual facilities, can vary widely. But for illustrative purposes, we estimate that company-wide, a large wholesale distributor typically could receive 110,000 cases per day or 550,000 cases per week. To break up cases and pallets in order to scan each unit within would require enormously expanding warehouse space, millions of dollars in sorting and scanning equipment, and many more employees and labor costs.

We also do not believe the Draft Guidance's instruction to scan every inbound case can be done without immense slow-downs in the delivery of healthcare. Given the time it will take to accomplish inbound scanning, we believe the ability of wholesale distributors to continue just-in-time delivery of needed medicines to dispensers and patients would be compromised. Moreover, since such scanning at receipt would effectively repeat scanning upon sale just prior to shipment, there is no perceived security or other benefit from performing this duplicative action.

Consequently, we urge (through withdrawal of the Draft Guidance or otherwise) deletion of lines 329-344 to avoid catastrophic impacts upon pharmaceutical distribution and ultimately, patient access to needed medicines.

Finally, we are concerned with lines 355-358 and the provision that any "clerical error or other discrepancy" should be resolved within three business days. As many of these systems and processes are automated, we do not see the phrase "clerical error" as being accurate. We believe the word "clerical" should be deleted. Additionally, we see no reason for the time limit of three business days. If there is, as the Draft Guidance supposes, a mismatch between a product and data, such as missing or extra product, the purchasing trading partner is not going to be able to transact the product until the issue is resolved. Current experience with the VRS indicates that resolutions can sometimes take much longer than three business days. Trading partners do and will continue to work together to resolve such mismatches, but, as the product will not be transacted, it poses no safety or security risk. Consequently, we see no reason for the Draft Guidance to impose a limit of three business days.

c. Enhanced Verification, Section VII.A. and B. of the Draft Guidance.

Section VII A. and B. of the Draft Guidance address two aspects of verification – that trading partners must have systems and processes for verification of product (§582(g)(1)(C)); and that the product identifier on a return must be verified before a trading partner may resell the package or homogenous case. *See, e.g.*, § 582(c)(4)(D) (verification of saleable returns for wholesale distributors).

We are concerned with the Draft Guidance's expectation in Section VII.A. that verification occur within one minute.[70] Under the DSCSA, manufacturers and repackagers have 24 hours to respond to a verification request. § 582(b)(4)(C); § 582(e)(4)(C). As we explained in our discussion of the VRS (Section 3. b. of these comments), the VRS is intended to provide sub-second, verification responses given the tens of thousands of saleable returns that move through the supply chain every business day. However, VRS participants all recognized that the DSCSA gave manufacturers a full 24 hours to respond. We do not believe that the Draft Guidance should expect a shorter response time than what the statute provides for.

Moreover, only a few manufacturers and wholesale distributors, and an even smaller number of dispensers, are using the VRS. All trading partners would have to join the VRS in order to return a one-minute verification. We believe the Draft Guidance's tacit instruction that all trading partners pay for and participate in the VRS is inappropriate.

We also raise the issue of verification systems and processes with regard to verification of saleable returns. Section VII.B. of the Draft Guidance 487-488 states only that, for a saleable return, the product identifier should be verified, as described in section VII.A of the Draft Guidance. Section VII.A., in turn, describes how manufacturers and repackagers respond to verification requests.

However, as has been described to the FDA, for verification of saleable returns, many wholesale distributors intend to verify against internal databases generated from the TI they receive from manufacturers (often referred to as "verification against replicate data"). Wholesale distributors using this method will maintain up-to-date information received from manufacturers to assure that products are not subject to a recall, an illegitimate product notification, or some other action that would prevent them from being returned to inventory for resale. However, we are concerned that Section VII does not seem to recognize verification against replicate data. Assurance from FDA that wholesale distributors may verify saleable returns against replicate data would be important, among other things, to avoid confusion that might otherwise arise with trading partners and during inspections.

d. "Validation" in Section IV. of the Draft Guidance.

The Draft Guidance twice mentions that trading partner systems and processes should be validated.

- Lines 197-200, "Although each trading partner should have its own individual validated system and processes for managing its product and data, FDA recommends that the enhanced system enable the interoperable integration of such individual systems to the degree necessary to allow appropriate access, efficient information sharing, and data security."

- Lines 206-208, "For the purpose of this guidance, the "data architecture" of the enhanced system refers to the type of data collected and the data validation policies and standards that

[70] Draft Guidance at lines 470-473.

govern how data is used, stored, managed, and integrated within and between organizations and individual systems."

FDA, thus, appears to assume the DSCSA systems and processes of ***all*** trading partners, including those of dispensers and wholesale distributors, are "validated." Validation has a very specific meaning under the FDC Act and implementing regulations, with serious legal and operational consequences, and the failure to comply with validation requirements renders drugs unlawful and adulterated under the FDC Act.

We are aware of no authority, or precedent, for requiring wholesale distributors or dispensers to validate any DSCSA systems and processes. Accordingly, we would recommend that the words "validated" and "validation" be stricken from the Draft Guidance.

e. Use of the term "Integration" in the Draft Guidance.

We are concerned also with the Draft Guidance's discussion of the importance of "integration" to the "enhanced system." For example, lines 198-200 state: "FDA recommends that the enhanced system enable the interoperable integration of such individual systems to the degree necessary to allow appropriate access, efficient information sharing, and data security." Also, "In addition … the trading partner's individual system should be integrated into the enhanced system, so that FDA, other Federal and State officials, and other trading partners (requestors) can submit a verification request and receive the response in an electronic, interoperable, and standardized manner."[71] "There are several possible data architecture models for how the data can be used, stored, managed, and integrated for the enhanced system."[72]

At the outset, we believe the Draft Guidance is confusing or conflating the concept of "integration" with "interoperability." The use of a common standard allows different systems to become interoperable whereas system integration is, we believe in this context, the intention of bringing a company's different systems into a single system, and/or bringing the systems of many or all companies into a single system, neither of which is required by the DSCSA.

We further disagree with the Draft Guidance's apparent assumption that interoperability requires a trading partner to have a single "system" that performs ***all*** of its DSCSA obligations, including:

- Receiving, holding, and providing transaction data;
- Verification; and
- Notifying trading partners of a product problem, such as an illegitimate product or a recall.

Trading partners already have business processes in place to conduct many of the activities the DSCSA requires; the processes often predate the DSCSA, such as processes for conducting supplier

[71] Draft Guidance at lines 466-469.
[72] Draft Guidance at lines 214-215.

and customer due diligence and for identifying and notifying customers who purchased recalled product. Newer interoperable processes, such as verification of saleable returns and exchange of transaction data in standard EPCIS file formats have proceeded without any greater integration into existing systems. Of course, systems are "integrated" to the extent that information is shared, used, and incorporated internally, as applicable. For example, a wholesale distributor has systems and processes in place to assure that trading partners are authorized before transacting with them and saleable returns processing includes checking to be certain the product is not under a recall. But these different internal systems and processes are not typically "integrated" into a single "system."

Trying to integrate all these different systems and processes, as the Draft Guidance seems to urge, is beyond the ability of the supply chain at this time, especially given all that must be accomplished by 2023. Nor do we believe that such integration is mandated in the law. Trading partners are also understandably very cautious of creating systems so integrated, that they could be vulnerable to a single intrusion or failure, either to their own system, or that of a trading partner they would be integrated with. Such disruptions could interrupt the delivery of needed medicines to patients. Nothing that is being done today precludes consideration of adding additional functionality in the future. However, such functionality is, and should remain, optional and to be developed only if the individual business determines it wishes to do so.

f. "Alerts" in Section VII.C. of the Draft Guidance.

Section VII.C., *Alerts for Illegitimate Product*, has generated considerable confusion among stakeholders. It is possible that section VII.C. rests within the greater context of notification of illegitimate product and recall notifications, both of which exist in current law. So, as an example, manufacturers are required to notify wholesale distributors of recalls to the wholesale level and, wholesale distributors, in turn, search their inventory to determine if any of the recalled product is in stock. Should a dispenser return that product to the wholesale distributor, the wholesale distributor will have updated its own DSCSA systems so that any product from the recalled lot is not returned to inventory for resale. Were a trading partner to attempt to verify with the manufacturer an identifier on a product that is part of a lot under recall, the manufacturer would, similarly, identify the product as under recall and that it should not be sold. If this type of notification between trading partners is all that is contemplated in section VII.C., we would have no concerns with the section.

We caution, however, that the Draft Guidance appears to misstate the obligations with regard to illegitimate product notifications. The Draft Guidance states that "FDA expects that the enhanced system will be able to provide a message or alert to the supply chain if a product has been identified as illegitimate or is the subject of a recall."[73] "A product's manufacturer or repackager should be responsible for updating trading partners and FDA with an alert identifying the illegitimate product using the enhanced system."[74]

This is not what the DSCSA requires. The illegitimate product notification requirements for manufacturers, wholesale distributors, dispensers, and repackagers are set forth in

[73] Draft Guidance at lines 501-503.
[74] Draft Guidance at lines 508-510.

§§ 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B), respectively. FDA recently summarized these requirements in the Final Guidance for Industry, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* (June 2021) at 3 (emphasis supplied):

> Section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all ***immediate*** trading partners ***(that they have reason to believe may have received the illegitimate product)*** not later than 24 hours after making the determination. FDA anticipates that the immediate trading partners to notify would include those to whom a trading partner has sold the drugs and in some cases, from whom a trading partner purchased the drugs.

Any FDA guidance, including Section VII.C. of the Draft EDDS Guidance, must accurately reflect the DSCSA's specific notification obligations.

Another concern with Section VII.C. is whether the Draft Guidance is assuming a far, far greater notification functionality, where a trading partner or FDA can send alerts across an entire "system" to ***all*** trading partners, ***at one time***. Lines 501-510 state:

> "As such, FDA expects that the enhanced system will be able to provide a message or alert to the supply chain if a product has been identified as illegitimate or is the subject of a recall.
> …
> A product's manufacturer or repackager should be responsible for updating the enhanced system with an alert to indicate when the product is recalled. The trading partner that submits a Form FDA 3911 should be responsible for updating trading partners and FDA with an alert identifying the illegitimate product using the enhanced system. [footnote omitted]

HDA acknowledges and agrees that the DSCSA imposes upon trading partners the duty to notify other trading partners under the specific conditions set out in the statute. However, and as we explained above, a nationwide network, whether to carry tracing requests, transaction data, or alerts, that links all trading partners to each other and to government authorities, does not exist, cannot be built by 2023, and is not required by the DSCSA.

We believe trading partners intend to continue to use existing methods for communicating with other trading partners about product problems. If the Draft Guidance assumes something different, a "system" for all communications, to everyone, at once, we do not see industry voluntarily building and universally participating in such a system absent a clear statutory mandate. We see significant practical and technological hurdles, including that in order to meet this expectation, this network would have to enable thousands of manufacturers to communicate messages to hundreds of wholesale distributors and hundreds of thousands of dispensers.

g. Other issues.

We raise additional concerns:

- Footnote 19 of the Draft Guidance defines "product tracing information" as TI, TH, and TS. However, the requirement for a supplier to provide the TH to a purchaser sunsets in 2023 (§ 582(k)(1)). We believe any guidance related to the 2023 requirements should specifically recognize that the requirement to provide TH sunsets in 2023.

- In lines 274-276, the Draft Guidance describes the need for the product's serial number and expiration date to be incorporated into TI in 2023, with the implication that provision of the product's NDC number and lot number in TI are not new requirements. This representation is not technically accurate as not all transactions include lot number in TI, *e.g.*, wholesale distributors that directly purchased a product from the manufacturer do not currently have to provide lot number in TI. § 582(c)(1)(A)(ii)(II). However, in 2023, all these data elements will be included, for the first time, in the product identifier which must be included in TI. § 582(g)(1)(A) and (B). We recommend clarifying this language and aligning with the requirements and language of § 582(g)(1)(A) and (B).

- HDA also urges FDA to consider whether any other legal and administrative obligations may be triggered by issuance of a final version of the EDDS Draft Guidance. In particular, we believe that agencies are subject to additional analytical obligations when their proposals for regulated entities could have an annual effect on the economy of $100 million or more and/or if proposals raise novel legal and policy issues. For example, it is likely that the total cost for the entire supply chain to implement the Draft Guidance's provisions would easily exceed $100 million given that having to change or alter what has been under development for the last seven years in order to implement the Draft Guidance's "enhanced system" would be exceedingly costly. Analytical and other requirements under the Paperwork Reduction Act (PRA) may also apply.

* * *

HDA thanks FDA for this opportunity to comment on the Draft Guidance. We urge its immediate withdrawal as it predominately sets out an "enhanced system" that is not what Congress intended or enacted in the DSCSA. As a result, the Draft Guidance fundamentally differs from what industry has expended seven years and millions of dollars to build in order to comply with 2023 requirements. The "enhanced system" does not exist and, even if the agency did have the authority to implement it as described in the Draft Guidance, it could not be built by November 27, 2023.

If you have any questions, please contact me at 703-885-0240 or aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs