Healthcare Distribution Alliance

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Re: Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments, 87 Fed. Reg. 67047 (Nov. 7, 2022) Docket No. FDA-2022-N-2671

Dear Dr. Jung and Ms. Green:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments regarding the agency's Public Meeting and Request for Comments regarding Drug Supply Chain Security Act [DSCSA] Implementation and Readiness Efforts for 2023; 87 Fed. Reg. 67047 (Nov. 7, 2022), Docket No. FDA-2022-N-2671. We greatly appreciate the agency's efforts to guide implementation of the DSCSA and to assess industry readiness for meeting the important November 27, 2023 deadline.

HDA believes that the supply chain is at a critical juncture in its effort to establish the systems and processes needed to meet this important security deadline. Consistent with surveys HDA has conducted and statements made to FDA at the December 2022 public meeting, many in the supply chain have admitted that they will not be able to provide the data required to be transmitted with product transactions as of the November 27 deadline. Since DSCSA-covered products cannot be provided to healthcare entities without the required data, there is a real possibility, indeed, likelihood, that supply disruptions and prescription drug product shortages could occur after November 27.

In the discussion that follows, we explain the underlying challenges leading to such delays and detail our recommendations for flexibility that will alleviate these stresses on product availability and patient access. Moreover, we believe the narrowly tailored flexibility and stabilization considerations we lay out will accomplish these objectives without slowing the supply chain's progress toward full compliance and the more secure supply chain that Congress envisioned when it enacted the DSCSA.

ABOUT HDA

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

HDA has been active in DSCSA implementation from the very beginning. Long before the statute's enactment in 2013, HDA recognized the need to strengthen supply chain regulation, add uniformity, increase safety, bolster distributor licensure standards, and improve the identification of suspect and illegitimate products. We brought our concerns to Congress and actively participated in the multi-year legislative negotiations that evolved into the DSCSA.

Since enactment, we have continued our leadership role. Working with other stakeholders, we have developed guidances and convened stakeholders to sponsor important initiatives around barcodes, electronic data exchange, exceptions handling, verification, and more. We have provided educational materials, webinars, and conferences. For the last nine years, we have hosted our annual, two-day traceability seminar; at our most recent seminar in October 2022, there were 317 registered individuals, of which approximately 47 percent were attending for the first time.

Much progress has been made over the last nine years – with much more to be done to achieve the DSCSA's 2023 milestones. We briefly presented to the agency on December 8 at the public meeting and now expand upon those views. In our comments below, we will address:

- A summary of HDA's most urgent concerns that, if unaddressed, will surely lead to significant supply chain disruptions and product shortages.
- HDA support for recent FDA actions and pronouncements, including the tracing model the agency described at the public meeting.
- HDA reports on recent surveys of industry readiness.
- Considerations for covered products manufacturers and repackagers transact after November 27 where the manufacturer/repackager is not able to provide serialized data[1] to its customer, including our views on potential issuance of enforcement discretion and exemptions from § 582(g)(1)(A) and (B)[2] requirements.
- The opportunity for additional FDA leadership regarding product tracing.

COMMENTS

[1] Throughout this comment, for ease of use and clarity, we often refer to "serialized data" which means, in compliance with § 582(g)(1)(A) and (B), the interoperable, electronic provision of transaction information (TI) that includes the identifiers for the products that are the subject of the transaction.

[2] Section 582(g)(1)(A) states: "The transaction information and the transaction statements as required under this section shall be exchanged in secure, interoperable, electronic manner in accordance with the standards established under guidance" issued by FDA regarding unit level tracing and standards for interoperable data exchange pursuant to § 582(h)(3)-(5). Section 582(g)(1) (B) states: " The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction."

1. Summarizing HDA's Most Urgent Concerns

a. We strongly urge narrow alternatives to broadly delaying § 582(g)(1)(A) and (B) requirements for manufacturers and repackagers.

Our members report that manufacturer and repackager readiness to meet the requirements of § 582(g)(1)(A) and (B) is very uneven. Many suppliers to wholesale distributors do not know when they will be able to send complete and accurate product identifiers in TI in an EPCIS[3] event file. Wholesale distributors report that, despite repeated efforts at communication, some manufacturers continue to not respond at all about their plans for meeting their 2023 obligations. Given the varying states of readiness, we expect that some stakeholders may request broad enforcement discretion from the agency to, in effect, put off the November 27 deadline for these requirements.

HDA and its members strenuously oppose any broad grant of enforcement discretion that relieves all manufacturers and repackagers from § 582(g)(1)(A) and (B) requirements for some period of time. For those suppliers that are not ready to send product identifiers in TI in an EPCIS event file by November 27, 2023, there are other avenues that should be pursued in the alternative, specifically, obtaining on a company- and product-specific basis, exemptions from § 582(g)(1)(A) and (B) pursuant to § 582(a)(3)(A)(iii). As we discuss in section 4.c. below, though by no means ideal, narrow exemptions will be far less disruptive and costly to the supply chain than a grant of broad enforcement discretion that effectively extends the compliance date for interoperable data exchange beyond November 27, 2023.

b. To avoid product shortages and supply chain disruptions, trading partners will need flexibility to manage data and file-related problems during a stabilization period.

Since 2015, trading partners have been using the Advance Ship Notice (ASN) to electronically provide and receive TI and the Transaction Statement (TS). The ASN was an established electronic data interchange that trading partners had long used to exchange shipping and other business-related data. While it was not easy to modify the ASN to accommodate TI and TS, this electronic data interchange had been routine between trading partners. The ASN, however, cannot accommodate product identifiers in TI, which necessitates changing, by November 28, to the EPCIS global standard that FDA has recommended.[4] Additionally, the ASN is not a global standard and so cannot satisfy the DSCSA's 2023 data exchange and interoperability requirements.

However, moving from lot level data and the familiar ASN to item-level data in the new EPCIS event file format and interoperable data exchange is a very complicated transition for trading partners. The EPCIS event file format is new to most trading partners and more complex

[3] Electronic Product Code Information Services (EPCIS) is a global GS1 standard for creating and sharing event data interoperably within an organization and with its trading partners. *See* DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry (July 2022) (Interoperable Data Exchange Draft Guidance). Sending and receiving serialized data in an EPCIS event file is how suppliers and wholesale distributors will meet § 582(g)(1)(A) and (B) requirements.

[4] *See* Interoperable Data Exchange Draft Guidance.

than the ASN. Being able to capture and provide product identifiers in the EPCIS event file – and to do so accurately – is also complex. Many manufacturers and wholesale distributors t have worked diligently and will be able to provide and receive product identifiers in TI in EPCIS event files by the statutory deadline, but these trading partners will nevertheless need flexibility during the difficult transition that will follow November 27, 2023.

This need for initial flexibility for a period of time after November 27 is driven by what we anticipate will be a substantial rate of unit level data- and file-related errors and exceptions. Based upon the reports of our wholesale distributor members' experiences thus far with manufacturers who are able to send serialized data, exceptions and errors are most commonly arising from file format problems and data in the file that could not be processed (such as inaccurate master data and incorrect data formats). As a result, wholesale distributors have observed mismatches, where the digital record in the EPCIS data file does not match the product received.

We emphasize that these types of data and file-related errors and exceptions are not surprising given the complexity and novelty of interoperable data exchange using EPCIS event files that include product identifiers. However, the DSCSA appears to give no flexibility in how these data and file-related issues must be treated. Under the DSCSA, a wholesale distributor cannot accept a product after November 28, 2023 if it does not have TI with that product's identifier in an EPCIS event file. If a wholesale distributor discovers a problem with the data it received after November 27, 2023, it cannot resell the product to a dispenser.

Our members believe that up to 35 percent[5] of all DSCSA-covered products, initially, could be subject to data or file-related errors and exceptions, resulting in stopping hundreds of thousands of drug packages from moving forward to patients each day. From a practical perspective, wholesale distributors do not have the physical space in their warehouses to hold that much product and segregate it from saleable inventory. Wholesale distributors and their established manufacturer trading partners do not have the resources or capacity to individually address each of these hundreds of thousands of anticipated data or file-related problems, particularly as the process for each product could take weeks or months to resolve.

Given the sheer ***number*** of products that would stop moving through the supply chain because of a data or file problem, the impacts upon healthcare delivery and wholesale distributor operations would be severe and new shortages would be very likely. Moreover, if every data or file-related problem automatically resulted in having to treat products as suspect, wholesale distributors and manufacturers would swiftly be overwhelmed in suspect product investigations. Severe burdens on their collective ability to continue timely delivery of medicine to patients would follow.

Established authorized trading partners electronically exchanging TI with product identifiers interoperably in an EPCIS event file need a period of flexibility to stabilize these new

[5] Unfortunately, this 35 percent represents the data and file-related problems wholesale distributors are observing now, among their ***most engaged and committed*** manufacturer suppliers. The error rates will likely be much higher for those who are not engaged, who are putting off needed investment and development until the last minute, or who are wholly ignorant of the November 27 deadline.

and very complex processes while also continuing to move needed medicines forward to patients. During this stabilization period, we suggest implementing the approach FDA adopted in its guidance on the grandfathering of product[6] without product identifiers.

Specifically, where two authorized trading partners are interoperably exchanging product identifiers, but a problem arises because of a data or file-related error or exception, the trading partner should be able to continue to purchase, receive, or sell the product, so long as there are no indicia that a product is suspect or illegitimate, apart from the data or file-related problem. The trading partners will continue to work, going forward, to improve software, coding and master data errors and stabilize their interoperable data exchange. We believe this initial flexibility will be crucial to ensuring continued supply of medicine and avoiding catastrophic shortages.

HDA has been working with stakeholders for many years on exceptions handling and published the "Exceptions Handling Guideline for the DSCSA"[7] in April 2022. Piloting and workshops pertaining to HDA's exceptions handling work are expected to continue.[8] We will be submitting further, more detailed information on this and other transition-related issues to FDA and will recommend that FDA provide urgently needed clarity and flexibility so trading partners can continue to deliver medicines to dispensers and their patients during this temporary stabilization period.

We emphasize that this stabilization period should not be confused with a grant of enforcement discretion – which we oppose for further reasons explained in section 4 below. Even if FDA delayed the effective date for compliance with § 582(g)(1)(A) and (B) another 10 years (which we would oppose), trading partners would still need this stabilization "beta" period. Systems this new and complex need to be used in the real, production environment regardless of when the requirement is effective.

c. Problems with the legibility of the product identifier continue to persist.

At the public meeting, HDA members raised the problem of DSCSA-mandated product identifiers becoming unreadable and illegible on product packaging.[9] It has been discovered that on some products, the required machine readable, 2-dimensional (2D) data matrix barcode ***and*** the human readable interpretation of that 2D barcode (collectively referred to here as the "product identifier") become illegible over time. Because of the label stock and/or ink used, these products cannot withstand even routine handling and stacking of cartons and packages during storage. Members report that simply picking up an affected bottle can result in the product identifier rubbing off easily, with the ink leaving residue on hands and clothing. Long before a product's expiration date, the printed product identifier may fade and become unreadable.

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[6] Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier (September 2018).
[7] Prepared by technical experts of the HDA Exceptions Handling Work Group, these guidelines were developed to address exceptions that may arise when passing or failing to pass DSCSA-required information to authorized trading partners.
[8] For example, HDA is working again on exceptions with the Partnership for DSCSA Governance (PDG), https://dscsagovernance.org/, an industry consortium of pharmaceutical supply chain stakeholders in a public-private partnership with the FDA.
[9] *See, e.g.,* Slides 31 and 32 of Day 2 of the public meeting.

If the product identifier fades, the 2D data matrix barcode cannot be scanned, and the human readable interpretation of the barcode cannot be read manually. If the product identifier cannot be scanned or read, the product cannot be sold, verified, traced, or returned to inventory for resale.

Products with faded, unreadable product identifiers pose additional challenges for dispensers and product return processes. HDA has long estimated that dispensers return to their wholesale distributor supplier approximately 3.5 to 4 percent or 119 to 139 million units[10] of sold products annually. The return of products that are saleable to inventory for resale and distribution lessens the potential for product shortages and is enormously important to the economic vitality of wholesale distributors and dispensers. If the dispenser attempts to return a product with an unreadable product identifier to its wholesale distributor, the wholesale distributor will not be able to accept the product as a saleable return because it cannot verify the product identifier or associate the product identifier with its TI.

We do not know the full scope of this labeling problem, but indications are that it is considerable and could result in otherwise good product having to be removed from the supply chain. We urge FDA to address this problem with manufacturers and repackagers.

2. HDA Support of Recent FDA Actions and Pronouncements

a. HDA supports a recent Draft Guidance and a Proposed Rule.

In our prepared remarks at the public meeting, we thanked FDA for two important releases – the 2022 revised draft guidance on Standards for the Interoperable Exchange of Information (Interoperable Data Exchange Draft Guidance) and the National Licensure Standards for Wholesale Distributors and 3PLs Proposed Rule (Licensure Proposed Rule). Below, we expand upon those remarks.

We submitted comments strongly supporting the Interoperable Data Exchange Draft Guidance.[11] This Draft Guidance recommended that trading partners use EPCIS to provide TI and TS in DSCSA-covered transactions. We believe EPCIS is the only current standard that both meets the requirements of the law and supports interoperable data exchange. This Draft Guidance was an important and needed recognition of the commitment to EPCIS many trading partners had already made and was a needed "push" for those who had been putting off the investment needed to implement this international standard.

We join with numerous other commenters and public meeting speakers who asked that FDA finalize the Draft Guidance swiftly and that the agency expressly acknowledge that portals are compliant with the DSCSA. Portals have been in use for many years. Trading partners and service providers have developed and built them as part of DSCSA implementation and they are an important business-to-business solution that eases burdens for dispensers. A dispenser relying upon portals does not have to undertake the considerable IT build and other expenses to be able to receive EPCIS event files into its own systems. Instead, the interoperably exchanged TI and TS is posted to the portal

[10] *See*, *The Role of Reverse Distribution* (HDA Research Foundation 2018). While the number and percentage of returns may vary over time, we believe that 3.5-4 percent tends to remain relatively stable.
[11] HDA's comment on the Interoperable Data Exchange Draft Guidance is here, https://www.regulations.gov/comment/FDA-2014-D-1981-0003

that the dispenser can then access, significantly lessening their costs and effort to come into compliance.

We appreciate FDA's oral statements at the public meeting that the omission of a reference to portals was simply because the agency did not intend to provide examples or to specify a single technology. However, the frequent and emphatic requests that the agency specifically address portals demonstrates confusion and uncertainty among stakeholders that would be eased with the agency's specific acknowledgment of portals as acceptable for 2023 DSCSA compliance.

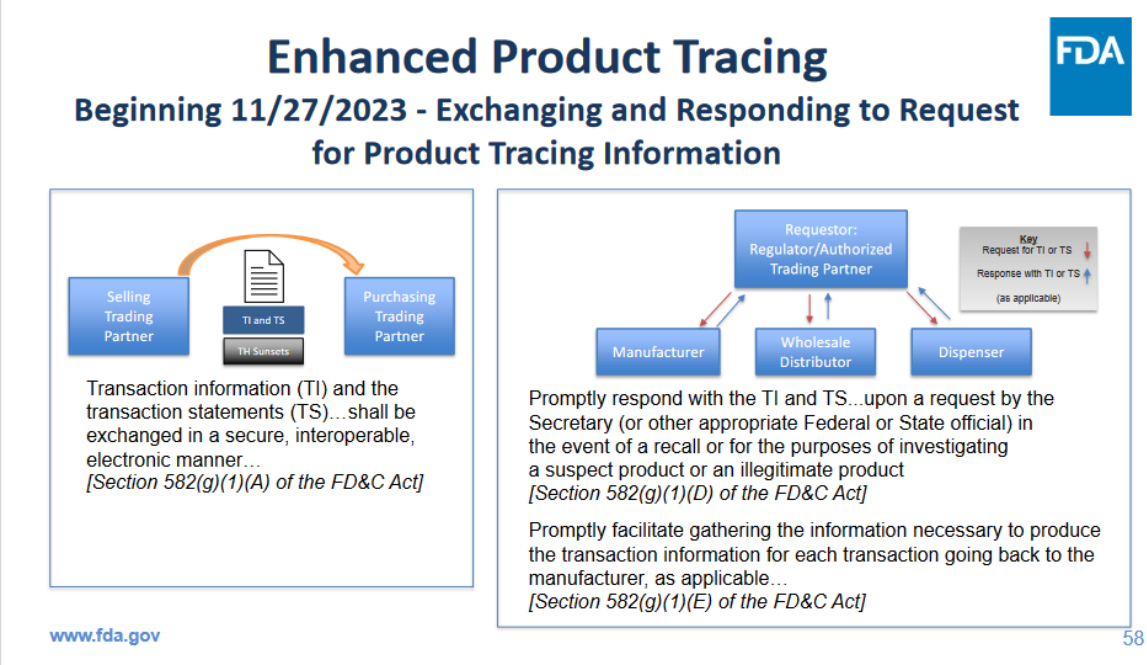
Second, we thank FDA for the issuance of the Licensure Proposed Rule which will, when final, establish national standards for the licensure of wholesale distributors and 3PLs. As we stated during the public meeting, the overall length of our written comments, chart, and preemption discussion should not be interpreted as profound disagreement with the Proposed Rule.

Rather, because wholesale distributors and 3PLs will be living with this rule for a long time once it is finalized, we wanted to be sure that the standards not only advance security and integrity but can also be operationalized. Further, where the proposed standards for wholesale distributors and for 3PLs differed, we recommended alignment and specific wording to make the two sets of requirements parallel, when possible, to facilitate implementation by trading partners and oversight by regulators. Our preemption analysis anticipated the comments of other stakeholders and we sought to support the agency's own conclusions that state licensure requirements need to be the same as the federal standard. HDA supported much of the Licensure Proposed Rule, and we look forward to working with FDA on its finalization.

b. HDA supports FDA's tracing model described at the public meeting.

In statements at the public meeting, we understood FDA as espousing and supporting important interpretations of how tracing will work in 2023 and beyond. Slide 58 included in the posted meeting materials[12] describes a tracing model we believe is consistent with the DSCSA and conforms to the interoperable solutions industry has been building:

[12] The FDA public meeting PowerPoint is available here.



Importantly, the right panel of slide 58 recognizes that tracing involves one request at a time, with a trading partner responding with the TI and TS (for a regulator-initiated request) or information (for a trading partner initiated-request) in its possession. Slide 58 does not assume that all transaction data reside in a single repository or linked repositories and does not assume that a single request will return all transaction data associated with a single product identifier. Nor does Slide 58 assume that a trading partner that received a tracing request must then initiate the next tracing request to its customer or supplier trading partner. As we understand the model set forth in slide 58, we believe it comports with the DSCSA, and that it is achievable based upon the TI and TS that trading partners will be interoperably exchanging (the left side of side 58).[13]

In section 5 below, we discuss additional guidance we believe would be helpful for the agency to provide regarding implementation of the tracing model presented in slide 58.

[13] The compliant and achievable tracing model described in Slide 58 is in contrast to the Draft Guidance, Enhanced Drug Distribution Security at the Package Level Under the DSCSA (EDDS Draft Guidance). The EDDS Draft Guidance states: "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…. 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." EDDS Draft Guidance at lines 432-439. HDA discussed in comments to the EDDS Draft Guidance why the functionality seemingly described and expected was not required by the DSCSA, was not being built by industry, and could not be operationalized by November 27, 2023. *See* https://www.regulations.gov/comment/FDA-2020-D-2024-0017.

3. Industry Readiness

a. HDA surveys show progress and varying degrees of readiness.

As we briefly discussed in our oral presentation at the public meeting, HDA has completed surveys on 2023 readiness – the Annual Serialization Readiness Survey[14] and the 2022 EPCIS Implementation Benchmarking Survey.[15] HDA has also recently surveyed dispensers. These surveys are good indicators of where trading partners are on the path to the November 27 deadline.

The HDA Research Foundation has conducted the Annual Serialization Readiness Survey for the last seven years to gauge the status of manufacturers and wholesale distributors in meeting the DSCSA's product serialization requirements. Forty-eight (48) manufacturers and twenty-nine (29) distributors responded to our June 2022 survey. Respondents included sixteen of the 2020 top 20 pharmaceutical manufacturers by sales.

Among manufacturer respondents, 57.5 percent were already aggregating data for all SKUs (stock keeping units), meaning they could capture the serial numbers of all the units in a case, and associate those package-level product identifiers to the case-level product identifier. This aggregation is critically important to 2023 interoperable TI requirements because if a manufacturer cannot capture the product identifiers of the units when they were packed into a case, it would have to open the sealed case and scan each unit within the case in order to generate the TI with product identifiers when it sells the case. (We return to this very important DSCSA legal requirement, effective on November 27, in section 4 below.)

We also asked if a responding manufacturer could send serialized data to its customers, that is, whether it could send TI that includes product identifiers for the packages it sold.[16] This aspect of manufacturer self-reported readiness is concerning. In June 2022, only 32 percent of responding manufacturers were sending serialized data to their wholesale distributor customers upon shipment. Sixty-six percent said they intended to be doing so by November 2022 – how many met this internal deadline is unknown. Two percent of manufacturer respondents were still unsure of when they would provide serialized data to their wholesale distributors.

Consistent with these results, as of January 2023, our members report that generally, few manufacturers are sending serialized product identifier data and, if they are, they may not be sending complete or accurate data and/or are not sending data for all their SKUs. Many have been shifting their timeline into 2023.

Among the twenty-nine (29) wholesale distributors responding to the survey in June 2022, 62 percent reported being able to accept serialized data at that time. Of those that could not accept data as of the survey time frame, 64 percent planned to be ready sometime in 2022 and 36 percent in 2023. The remainder responded they would be ready by 2023.

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[14] The final report on the Annual Serialization Readiness Survey, conducted by the HDA Research Foundation, is available here.

[15] The final report on the 2022 EPCIS Implementation Benchmarking Survey, conducted by the HDA Research Foundation, is available here.

[16] Pursuant to § 582(g)(1)(B), beginning November 27, 2023, TI "shall include the product identifier at the package level for each package included in the transaction."

HDA's 2022 EPCIS Implementation Benchmarking Survey was conducted in the first and second quarters of 2022. We surveyed the same 48 manufacturers and 29 wholesale distributors about their plans to adopt and implement EPCIS. We were pleased to see that 90 percent of manufacturer respondents stated they had adopted EPCIS 1.2, which is the minimum standard for being able to support the data exchange necessary for DSCSA compliance. There has been a substantial upward trend in the necessary connections manufacturers are making with their wholesale distributor customers.

In late September through early October 2022, HDA partnered with a polling firm to survey pharmacists regarding the pharmaceutical supply chain and other matters. There were 502 total responses from 173 retail pharmacists, 144 hospital pharmacists, and 167 independent pharmacists.

Two survey questions asked pharmacists about the DSCSA. Responses from independent pharmacists showed that only 60 percent were "very" or "somewhat" familiar with DSCSA. Forty-nine percent of independent pharmacists surveyed were not sure if they would meet the 2023 deadline.

b. The HDA surveys and FDA's public meeting reveal that some trading partners have a lot more work to do.

These survey responses are consistent with what numerous stakeholders stated at the public meeting regarding dispenser and manufacturer readiness. As to ***dispensers***, manufacturers and distributors reported that many do not understand DSCSA requirements. Recognizing this knowledge gap and the burdens upon dispensers if they must establish business-to-business connections to enable data exchange, many wholesale distributors and service providers have been intending to offer portals to ease dispensers' compliance challenges.

As to ***manufacturers***, the lack of readiness described in the HDA surveys and in statements at the public meeting constitutes a serious impediment to the ability of wholesale distributors to comply with 2023 requirements. Wholesale distributors cannot accept a product if the manufacturer does not send an EPCIS event file with the identifier of the product in a transaction. As was reported at the public meeting, obtaining master data from manufacturer suppliers continues to be hugely challenging for wholesale distributors. Certain pieces of master data, such as the Global Trade Identification Number (GTIN)[17] for each product, are necessary to enable a successful EPCIS interoperable data exchange. From our survey, 52 percent of distributors had received master data for up to 25 percent of products. Unfortunately, 24 percent of distributors reported receiving no master data from manufacturers.

Additionally, and as was also discussed at the public meeting, HDA members continue to report that some manufacturers have not responded to repeated requests to establish EPCIS connections. Setting up the EPCIS connection with a manufacturer can take weeks or even months. With so many manufacturers waiting – and all wanting to be onboarded last – there is not going to be enough time to secure all necessary connections by November 27, 2023. Without those connections, manufacturers will not be able to send TI with product identifiers and wholesale distributors will not be able to purchase and accept delivery of DSCSA-covered prescription products.

[17] The GTIN is used by a company to uniquely identify all of its trade items. A GTIN comports with standards established by GS1, an international standards-setting organization.

We caution that those manufacturers that receive and respond to HDA's surveys are a small proportion of all DSCSA covered product manufacturers. These few manufacturers are likely highly engaged in DSCSA implementation and aware of their legal obligations. Thus, it is possible, if not likely, that a significant percentage of covered product manufacturers are even further behind in their DSCSA implementation and thus may be wholly unprepared for November 27.

4. Addressing Lack of Readiness for November 27, 2023

As we discuss in the section above, some suppliers frankly revealed at the public meeting that they will not be able to provide product identifiers in TI in an EPCIS event file on November 27, 2023, either for all, or for some, of their products. During breakout sessions, manufacturers stated, for instance, that they have entire manufacturing production runs for which they do not know the identifiers for the products in sealed homogeneous cases and that these products will not all be sold by November 27. Indeed, we understand that some manufacturers made a business decision to defer DSCSA implementation and are ***still*** not capturing identifiers before products are packaged and sealed in homogeneous cases.

This means, we assume, that to lawfully sell such products after November 27, a manufacturer would have to open every sealed homogeneous case and scan the identifiers of the products within the case in order to generate the statutorily mandated product identifiers data for inclusion in TI. However, at the public meeting, manufacturers contended that because such actions would be expensive and impractical, they should be able to continue to sell products without providing their identifiers in TI, even after November 27. They also warned that if not excused from legal compliance with § 582(g)(1)(A) and (B), product shortages may result.

Because of these concerns, HDA suspects that manufacturers in such situations may seek broad enforcement discretion from the agency and/or attempt to obtain an exemption under § 582(a)(3)(A)(iii)[18] from their § 582(b)(1)(A) and (B) interoperable data exchange obligations. ***However, any such relief, unless very carefully limited, will cause profound difficulties and costs for wholesale distributors.*** Below, HDA describes these burdens and fundamental inequities.

[18] Pursuant to § 582(a)(3)(A), a trading partner may seek a "waiver," "exception," or "exemption" from § 582 requirements. Under § 582(a)(3)(A)(i), a manufacturer or other authorized trading partner may request a waiver from any of the requirements of § 582 if FDA determines that such requirements "would result in an undue economic hardship" and, if not otherwise eligible for a waiver, may obtain an "exemption." We do not believe any manufacturer should claim "undue economic hardship" and obtain a waiver from providing serialized data because it packaged products and sealed the case before capturing the products' serial numbers. Other manufacturers in the supply chain were able to accomplish this legal requirement that has been known for 9 years. The economic hardship is not "undue" simply because it was delayed for private business reasons. "Exceptions" under § 582(a)(3)(A)(ii) relate only product identifier requirements and are not relevant here. We therefore only refer to "exemptions" (§ 582(a)(3)(A)(iii)), which we believe are the ***only*** mechanism under § 582(a)(3)(A) available to a manufacturer or repackager seeking to avoid sending serialized data after November 27, 2023.

a. Suppliers that do not send serialized data by November 27, 2023, create enormous burdens and jeopardize interoperability for every downstream trading partner.

On November 27, 2023, many trading partners will be able to comply with the DSCSA's interoperable data exchange requirements by sending and receiving EPCIS event files with TI that includes product identifiers.[19] In this context, "interoperable" means that each trading partner link of the supply chain is dependent on the supplier before it in order to be able to meet its legal obligations to the downstream purchaser that follows. On November 28, a manufacturer or repackager that does not send an EPCIS event file with identifiers for the product transacted is both out of compliance ***and*** its failure makes compliance for its downstream wholesale distributor customers wholly impossible.

For the TI to include product identifiers and for TI and TS to be interoperably exchanged from supplier to wholesaler distributor and from wholesale distributor to dispenser, the process must begin with the manufacturer creating an EPCIS "commissioning event." This commissioning event typically occurs during the manufacturer's process of serializing a product and packaging – the commissioning event is created for a product's unique serial number. This event is then reflected in the EPCIS file the manufacturer provides to its wholesale distributor customer.

Other significant "events" for that serial number are captured in an EPCIS event file as the product moves through the supply chain. For example, the wholesale distributor's shipment of the product and/or container with the product will create another commissioning event for that container's serial number and this event and the manufacturer's original commissioning event will be shared in an EPCIS event file provided to the purchaser. The ability of the wholesale distributor to create and provide an EPCIS event file with product identifiers when it sells the product to its customer depends upon being able to match that product's identifier to the TI it received from the manufacturer. It is through this series of events reflected in EPCIS event files that trading partners achieve the statutorily mandated interoperable data exchange and can interoperably trace products at the package level.

After November 27, the ability of a wholesale distributor to comply with the DSCSA and provide an EPCIS file to its customer with identifiers for the products in the transaction depends upon its receipt of the commissioning event data for those products in an EPCIS file from the manufacturer it purchased the products from. After November 27, wholesale distributor systems ***cannot provide what was not received***. If a wholesale distributor does not receive product identifiers in TI in an EPCIS event file from a supplier for product transacted after November 27 as the law requires, it is unable to generate an EPCIS event file when it sells that product to a customer.

For products purchased after November 27, if the supplier cannot provide product identifiers in an EPCIS event file, it should not be up to wholesale distributors to "fix" the broken chain of interoperability or to devise some way to provide to their downstream customers the product identifiers they did not receive from a non-compliant trading partner. We emphasize that the technical experts of HDA members see ***no*** operational fix for a product sold by the supplier after November 27 without its identifier in TI except by removing that product entirely from a wholesale distributor's DSCSA systems and processes until the supplier complies with the law and is able to send an EPCIS event file with accurate product identifier data in the TI.

[19] As has been discussed previously, no other standard except EPCIS can accommodate the interoperable exchange of product identifiers in TI that the DSCSA requires.

Further, once wholesale distributors switch systems on November 27 and begin receiving product identifiers in EPCIS event files for DSCSA-covered transactions, they ***cannot*** satisfy DSCSA interoperable data exchange requirements through any other means, including continued use of ASNs. Additionally, our wholesale distributor members cannot operate dual systems whereby some products are purchased, accepted, and resold using TI managed in an EPCIS-system while other products continue to be managed under the prior system of receiving TI in an ASN. As discussed previously, the ASN will ***not*** satisfy 2023 requirements: it is not an international standard and there is no software or other feasible solution that would allow ASNs to carry product identifiers. Even if continuing the ASN were feasible and compliant (it is neither), regressing temporarily back to this 2015 DSCSA process would require wholesale distributors to spend millions of dollars in system changes and countless months of work.

Wholesale distributors should not be asked to even attempt such an effort and incur such expense because some suppliers are unable to meet their own statutory requirements on time.[20]

b. Though there are suppliers who will not be ready to send serialized data on November 27, 2023, many other trading partners are working towards full compliance.

In contrast to the suppliers who will not be able to comply with these long-known requirements of the DSCSA, many manufacturers, repackagers, and wholesale distributors are ready or will be ready to comply by November 27, 2023. These prepared trading partners have changed their operations, hired and trained the employees, purchased the equipment, participated in work groups to write the standards and guidance, and developed the systems and IT infrastructure. These manufacturers and repackagers are working to be ready to send serialized data to their customers and these wholesale distributors intend to "turn on" their systems and begin receiving, storing and providing EPCIS event files with product identifiers for each package in a transaction. These trading partners have prepared for nine years to meet the DSCSA deadline and to sell, purchase, and deliver needed medicines to customers for their patients in full compliance with the law.

Given that many trading partners are working to be ready on November 27, granting any broad enforcement discretion or exemptions that widely delay the effective date for compliance with § 582(g)(1)(A) and (B) requirements may have counter-productive and unwelcome effects. Those who have made the efforts and investments to come into compliance, would, in effect, be punished and those who have elected to not make the same timely and costly investment would be rewarded for avoiding a long-known legal deadline.

c. Any relief from § 582(g)(1)(A) and (B) should be carefully scrutinized by the agency and very limited, if granted.

In light of the foregoing, HDA and its members strenuously oppose ***any*** broad grant of enforcement discretion from the requirements in § 582(g)(1)(A) and (B) that excuses ***all*** trading partners from exchanging TI and TS in a secure, interoperable, electronic manner in accordance with

[20] In a similar vein, some wholesale distributors report an expectation that it should be up to wholesale distributors to fix the problem of any inaccurate product identifier data sent by manufacturers because the manufacturer is unable to generate accurate data on its own. We do not believe such an approach is compliant with the DSCSA. FDA has emphasized, and we agree, that interoperability for purposes of § 582(g)(1) compliance encompasses, among other things, the ability to exchange TI and TS "accurately, efficiently, and consistently." Interoperable Data Exchange Draft Guidance at lines 132-134.

the EPCIS standards and including product identifiers in TI for each package in the transaction. As discussed in section 1 above, a stabilization period – and ***not*** a delay in effective date – is critically important to ensure needed medicines can continue to be delivered to patients while trading partners continue working together to stabilize their EPCIS interoperable data exchange.[21] We believe that any broad grant of enforcement discretion that delays implementation of interoperable exchange of serialized data would especially burden downstream trading partners, would frustrate efforts to achieve product tracing, and might support reluctant suppliers who are continuing to delay the necessary DSCSA investments other trading partners have already made.

In lieu of broad enforcement discretion and industry-wide delay, we ask that the agency require any trading partner seeking relief from § 582(g)(1)(A) and (B) to proceed via a request for an exemption under § 582(a)(3)(A)(iii). We also urge FDA to establish stringent requirements to obtain, and guardrails around, any exemptions the Agency does grant. Such limitations and requirements, in our view, should include the following:

- Each manufacturer/repackager should submit a separate, specific exemption request for ***each*** product by its National Drug Code ((NDC) and including relevant GTINs) it seeks to excuse from § 582(g)(1)(A) and (B). This is because a manufacturer/repackager typically begins sending serialized data in EPCIS event files by NDC and builds to sending EPCIS event files for their entire product line over time.

- To be operationalized without disrupting the interoperable data exchange that is "live" for compliant products and transactions, it is imperative that any exemption for a covered product operate as product-specific waivers and exemptions do now – ***no*** DSCSA obligations should apply to that product and the product should be wholly exempt from data exchange and other DSCSA requirements, while it moves through the supply chain until its expiration.

    - A product so exempted would be treated like any other product that is outside the DSCSA's jurisdiction, such as over-the-counter and veterinary drugs.
    - From the wholesale distributor perspective, the distributor would "turn off" its DSCSA systems as to that exempt product, and therefore would not expect to receive TI and TS for that product at time of purchase and would not generate and provide TI and TS to a customer at time of sale.[22]
    - Further, as a trading partner is not obligated to receive or generate transaction data for an exempt product, it will not be possible to initiate or respond to a tracing request for that product as the data will not exist.
    - Even though a product is exempt from DSCSA requirements, the exemption could specify that trading partners should nevertheless continue to apply their

[21] As we also discussed in section 1, we believe a stabilization period to work through interoperable data exchange issues in a production environment will be necessary regardless of the effective date of § 582(g)(1)(A) and (B) requirements. Delaying the effective date will not change the need for a stabilization period and the flexibility trading partners need.

[22] We discussed above that, once wholesale distributors change to receiving and providing TI in EPCIS event files, they cannot also use the ASN for receipt and provision of TI. Wholesale distributors cannot simultaneously operate two separate "DSCSA IT systems" to accommodate non-compliant suppliers who attempt to force them to continue to use ASNs for DSCSA data. This is why it is vitally important for a supplier to obtain a product-specific exemption from DSCSA requirements and that it remain in effect for that NDC until the supplier can comply with § 582(g)(1)(A) and (B) and provide TI, including accurate product identifiers, in an EPCIS event file.

systems and processes around identification and management of suspect and illegitimate products.

- Given past delays and to incentivize speedy compliance, we believe any exemption FDA approves should be very specific and clear in scope, with a firm deadline.

- The exemption should address what happens once the product exemption granted by FDA expires when there is product still in the supply chain that was temporarily under the exemption. The product already in inventory and on store shelves will not have any transaction data supporting it and the FDA exemption should be clear as to the treatment and status of such product.

- The manufacturer should provide to its purchasing trading partners a clear attestation, in writing, that FDA has approved an exemption for its NDC and include a full description of the scope of the exemption granted as well as its effective and ending dates.

We urge FDA to publish a notice of how it will process requests for exemptions from § 582(g)(1)(A) and (B) requirements as soon as possible. This notice should also explain what should be included in the request to enable speedy action and that all such requests should be submitted to the agency by a specified date, such as not later than six months before the DSCSA's deadline, *i.e.,* by May 27, 2023.

Based upon the comments in breakout sessions at the public meeting, we urge close scrutiny of requests to sell, after November 27, 2023, covered products packaged in sealed, homogenous cases without capturing the identifiers for the products in the case and providing them in an EPCIS event file. A manufacturer in this situation does not need – and in our view should not receive – an exemption from FDA when it can open the sealed cases, scan the products within them, and generate the data it is legally required to provide.

5. Product Tracing

As we address above, slide 58 from the FDA public meeting appears to describe a model for tracing in which a trading partner receives an appropriate request from a regulator or an authorized trading partner and provides, depending upon the requester, the TI and TS or other information in its possession. In slide 58, we believe FDA has begun to articulate a model for tracing requests and responses that is compliant and achievable. There are, however, numerous outstanding issues regarding tracing where we believe greater clarity from FDA would be useful for trading partners and other stakeholders, including state regulators.

a. Without product identifiers included in the EPCIS event file, tracing at the package level is impossible.

As explained above, the wholesale distributor's ability to send an EPCIS event file with product identifiers TI when it sells the product to its customer depends upon being able to match that product to the EPCIS event file received from the manufacturer. This series of EPCIS events, interoperably exchanged from manufacturer, to wholesale distributor, to dispenser, enables, among other things, the tracing of product at the package level in response to an appropriate request.

It is imperative that FDA, state regulatory authorities, and other officials understand that if a wholesale distributor or dispenser did not receive product identifiers in an EPCIS event file, it cannot provide tracing data at the package level in response to a request. Interoperable tracing at the package level will not be possible if the wholesale distributor or dispenser did not receive item-level data for that product from its supplier.

b. More discussion, guidance, and education about tracing would be useful.

In our oral presentation at the public meeting, we expressed our hope for greater clarity around tracing – who may initiate a tracing request, when, and what the output of a tracing request will be. We believe that slide 58, discussed previously, is an especially useful starting point for additional guidance from FDA on tracing. Below we reiterate and expand upon the utility of such guidance and potential elements it could address.

Apart from the National Association of Boards of Pharmacy (NABP) efforts to leverage its own network to route tracing requests by state regulators to pharmacies and wholesale distributors already part of the NABP system,[23] only high-level design work has been done around how a federal or state regulator will communicate a tracing request to a trading partner. For requests originating outside the NABP network, it is unknown how FDA and other appropriate officials will initiate a tracing request and establish the authenticity of their request. Based on comments we have heard, we suspect that, apart from FDA, most regulators and other officials do not know the circumstances under which they may initiate a tracing request pursuant to § 582(g)(1)(D) and (E).

Additionally, the requester may not understand that the responder will:

- Only be providing the transaction data it possesses; and,
- Will not be obtaining tracing data from other trading partners.

FDA tracing guidance should also provide information regarding the expected output of a tracing request. Even though a trading partner would be providing only its own data, an EPCIS event file is very, very large and could potentially contain TI for hundreds or thousands of other products that are not the subject of the request. (An EPCIS event file can be 300 megabytes or larger.) An EPCIS event file in its native form cannot be read by most computers running standard office software and is too large to be sent via email. It is likely that the requesting authority will receive, at least at first, a summary or excerpt of an EPCIS event file with the TI and TS for the product(s) subject to the request rather than a raw EPCIS event file. As an investigation progresses, the requesting authority might ultimately need the full EPCIS event file but, at the outset, we believe it would be helpful for a clear understanding of what the initial tracing output will likely be in order to support a swift and useful government investigation.

We are also concerned about state and local authorities' expectations regarding tracing. The EDDS Draft Guidance's description of tracing through an apparent "communications hub" or via interconnected databases is not how tracing will work. Contrary to the EDDS Draft Guidance (*see,*

[23] HDA takes no position on the NABP tracing project. HDA was as an observer in the project and several HDA members have participated. As the project has been presented, NABP appears to be acting as a solution provider and is enabling a regulator to send a tracing request to a trading partner and for that trading partner to send back TI and TS in its possession. The project, as we understand it so far, appears to be compliant with the DSCSA.

e.g., lines 432-439), a single request will not produce a single response that will allow a requester to view product tracing information from all trading partners involved in transactions related to a specific product. What the EDDS Draft Guidance appears to contemplate does not exist and has not been built. Consistent with 582(g)(1), in responding to a tracing request from a regulator or other appropriate official, a trading partner will provide the TI and TS that it has.

Additionally, a trading partner's response to a tracing request by a government authority will not be automatic, such as is accomplished with tracking via Federal Express or the U.S. Postal Service. We do not believe the DSCSA assumes or requires this type of automated response. We expect that a trading partner's legal counsel and compliance experts will insist upon reviewing any regulator tracing request and the intended response before any response is provided.

Last, the development of a consistent format for a tracing request and response could result in clearer, swifter communication. Both NABP and PDG have been working on standardizing formats. In these comments, we take no position on particular solutions or formats but encourage efforts that bring more uniformity and predictability to tracing requests and responses.

There is, in sum, a great deal of uncertainty throughout the supply chain and likely among regulators around tracing requests and responses. We hope that FDA will use its authoritative voice and broad platform to provide more education and guidance in this area.

* * *

HDA wishes to reiterate its strong support for the DSCSA and for its requirements to exchange serialized data. They are an important milestone for American healthcare and patients. Slowly rolled out over ten years of implementation, this data exchange makes it possible for the first time in the U.S. pharmaceutical supply chain to trace covered prescription drug products at the individual package level. We encourage FDA to support our efforts to address the challenges we describe above so that this milestone can be met with as little impact on patient access and care as possible.

We thank FDA for this opportunity to provide further input regarding FDA's December 7 and 8, 2022 public meeting in the final year of this important milestone that will better protect patients and the supply chain. If you have any questions, please contact me at 202-964-4439[24] or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs

[24] Please note that HDA has moved offices as of Jan. 1, 2023. Our new address is in the footer of this letter and my new direct phone number is 202-964-4439.