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RE: Pilot Project Program Under the Drug Supply Chain Security Act; Request for Comments; 82 Fed. Reg. 33497 (July 20, 2017); Dkt. No. FDA-2016-N-0407

Dear Doctor Jung:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Pilot Project Program under the Drug Supply Chain Security Act; Request for Comments, 82 Fed. Reg. 33497 (July 20, 2017), Dkt. No. FDA-2016-N-0407 (“Notice” or “Pilots Notice”).

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.

OVERVIEW

HDA appreciates the further details FDA has provided on this Drug Supply Chain Security Act (DSCSA) Pilot Project Program. We view pilots as critical to developing the understanding and experience necessary for smoother implementation of the DSCSA. Learnings from the pilots conducted so far, whether facilitated by HDA or by our members, have been extraordinarily helpful in identifying the DSCSA’s operational challenges and testing possible solutions. FDA’s announcement offers the opportunity to pursue further pilot activity and aid collaboration among trading partners, which will, among other things, “reflect[] the diversity of the supply chain”, as required by the DSCSA in § 582(j) of the federal Food, Drug and Cosmetic Act (FDC Act).
In April and May 2016, HDA previously submitted comments to this docket and Dkt. No. FDA-2016-N-1114-0004 on FDA’s proposed pilot initiative. Our comments and cover letter are available here and here and are incorporated by reference. Before moving on to this new Notice and request for comment, we briefly reiterate some of our earlier points:

- FDA should articulate and come to consensus with stakeholders on DSCSA terms and responsibilities so that pilots can be based upon a common understanding of the statute’s legal requirements.
- Pilots should focus on testing processes that can be utilized regardless of how technology evolves between now and 2023.
- Pilots should be tightly focused in order to yield practical, actionable information that will help enable compliance with DSCSA requirements. We believe that modest pilots with well-defined goals are more likely to yield useful information.
- Given the complexity of achieving interoperability and DSCSA compliance within the statute’s timeframes, we urge clear articulation of DSCSA requirements and how a pilot may further compliance with those requirements.
- Pilots will best serve supply chain security and patient safety if they take a realistic approach that recognizes the layers of DSCSA protections, i.e., enhanced licensure requirements for third part logistics providers (3PLs) and wholesale distributors; transactions only between authorized trading partners; investigations of suspect product; greater controls on saleable returns; illegitimate product notifications; and exchange of transaction data.
- Pilots will be especially useful in informing how to implement DSCSA requirements without also increasing the burdens upon the parts of the supply chain that are already highly efficient and secure.

LEARNINGS OF THE SALEABLE RETURNS PILOT

Since submission of our previous comments to this docket, HDA has, with a working group of stakeholders, completed a pilot of methods for verification of saleable returns – the Saleable Returns Pilot. A larger working group has now begun the arduous task of developing one of the methods piloted – a verification router service that would allow a wholesale distributor to scan the product identifier bar code affixed to a package and route a query to the appropriate manufacturer for verification of the identifier.

HDA’s Saleable Returns Pilot, conducted in 2016 to evaluate potential methods to help meet the DSCSA’s 2019 saleable returns requirements, leads us to urge, even more strongly than before, the importance of well-managed pilots that focus upon 2023 compliance and commitments, without venturing into testing what the DSCSA does not require. The Saleable Returns Pilot was, relatively speaking, a straightforward pilot that tested different business processes to meet a single, well-defined DSCSA requirement. Still, the planning and execution of the Pilot took over 12 months of diligent work by highly skilled DSCSA experts within the participating manufacturers and wholesale distributors, as well as support of HDA staff, counsel, and an outside project manager.
Even with all the expertise, resources, and very narrow scope, the process was far more challenging than anticipated.

From this experience, HDA emphasizes the following takeaways:

- It is critical to come to consensus on what the DSCSA requires in 2023 so that pilots can test how to comply with those requirements.

- At the outset, any pilot should focus upon achieving compliance with specific, clearly defined DSCSA requirements that must be met by 2023. Because developing and running a DSCSA pilot is very complex, time-consuming and costly, we do not believe that scarce resources should be expended upon testing what the DSCSA does not require. With industry consensus, additional functionality and complexity can be added later, after the means for satisfying statutory requirements are identified and tested.

- Good project management is essential. Even so, a pilot will likely take longer than expected, require more effort than expected, and will challenge even the most experienced DSCSA experts.

Below, HDA addresses specific comments regarding the Notice and the questions FDA poses.

**PROPOSED PILOT TIMELINES**

HDA has concerns with timelines outlined in the Notice. Planning for pilots is made more challenging given that FDA does not intend to accept requests to participate in the program until the Office of Management and Budget has approved the proposed collection of information.

Greater concerns arise from FDA’s proposed deadlines. The Agency states participants should be ready to start their pilot project within four months of receiving a letter of acceptance from FDA and that the duration of pilot projects must not exceed six months. Final reports must be completed within 30 days.

Based upon HDA’s experience with previous pilots, these four and six-month timeframes seem overly optimistic, too prescriptive, and would be very difficult to achieve given the personnel and resource demands on participants. The necessary coordination among a pilot’s participants could easily extend beyond these allotted timeframes. Participants usually must budget for the possibility of participation in a pilot far in advance, and then allocate personnel and resources during a pilot’s execution.

Similarly, we do not believe that preparation of a final report within 30 days is realistic. Final pilot reports must be crafted to reflect the findings and views of all the participants, which can be an arduous and elusive task given that the participants often have very different priorities and perspectives – achieving accord can be especially challenging when pilot findings may burden particular trading partners and/or industry segments differently. Additionally, a pilot report would usually be written by participants who already have other full-time commitments. The report would also be subject to extensive internal and external review. The preparation of the HDA’s Saleable Returns Pilot final report took several months, not 30 days, after completion of the pilot’s execution phase. We believe a range of
90 days to 120 days is more realistic, and may need to be extended even further depending upon the pilot’s complexity.

Thus, HDA respectfully discourages FDA from placing restrictions and deadlines upon pilot programs that stakeholders must develop, fund and run themselves. Such constraints may deter stakeholders from electing to participate. These pilots are undertaken by industry, voluntarily and collaboratively, in order to test methods for complying with the DSCSA and to identify solutions to obstacles the requirements pose. Industry stakeholders will likely be dissuaded from dedicating the time, personnel or resources upon pilots which may not, due to time constraints, allow advancement of specific, actionable measures for 2023 compliance.

HDA and its members welcome FDA support and feedback in their pilot efforts. We believe it would be particularly useful if the Agency specifically confirmed industry approaches to DSCSA compliance in a timely manner so that stakeholders do not waste resources testing business processes FDA does not deem compliant.

We also support the Agency’s involvement as a clearinghouse for information on pilots. We agree that FDA can and should leverage its position to identify gaps in understanding. We support FDA widely disseminating information to industry about pilots that are under development or recruiting participants. FDA can also continue to educate stakeholders by publicizing the learnings from industry pilots. HDA commits to working with FDA to assist in identifying DSCSA pilots already undertaken and those that are planned so that the Agency can disseminate this information widely to encourage broad participation and sharing of pilot results.

**SPECIFIC AREAS FOR PILOTS**

In *Table 1* of the Notice, FDA identifies numerous possible subjects for pilot testing. As discussed below, HDA views “aggregation/disaggregation,” “exception handling/errors/inconsistencies,” and “interoperability” as priority areas of work:

**Aggregation and Inference**

HDA believes that aggregation and inference are critical to the success of product traceability. Supply chain efficiency is significantly aided by aggregation and inference and we do not believe that implementation of the DSCSA’s interoperable vision is possible without it. In our comments to FDA, available [here](#), we addressed the importance of pilots exploring aggregation and inference. As stated previously:

Without the benefit of inference, a wholesale distributor would not be able to transact in the aggregated quantities received from manufacturers, such as cases or pallets. Rapid, efficient receiving and warehousing actions would have to halt so that every sealed container holding multiple, serialized units of products, could be broken apart and individually scanned. Breaching and disturbing an otherwise sealed, intact container in order to scan individual units at the point of receipt also undermines security and makes it more difficult to identify product tampering and other potential problems. Breaking seals, opening containers and subjecting individual units of prescription drugs to needless handling also increases the risks of breakage, compromise of product integrity and otherwise rendering the product unsafe for patients. The ability of wholesale distributors to transact in aggregated sealed containers without scanning each item is
critical to supply chain security, product integrity and assuring the quick and efficient provision of medicines to patients.

May 16, 2016 HDA Comments to Dkt. No. FDA-2016-N-1114 at 2. HDA also recommended changes to the definitions of these terms that FDA had proposed.

The last 18 months and the Saleable Returns Pilot have continued to affirm the importance of inference and aggregation to supply chain efficiency – indeed, aggregation is necessary for one of the two preferred methods for verification of saleable returns. HDA members also note that they will need to be able to infer the contents of aggregated shipments in the deliveries they make to customers.

Because we believe aggregation and inference are so important to the entire supply chain, and so widely recognized as such, HDA recommends that pilots include these processes wherever possible.

As also discussed below, we believe that aggregation and inference pilots will be especially important given that aggregation is likely to result in periodic data errors – where a distributor or dispenser receives product from its regular supplier, but does not receive product identifier data for the product or receives incorrect product identifier data. We believe pilots will be especially useful in documenting these aggregation exceptions, and for testing processes for resolving them efficiently and securely.

Exceptions Handling

As trading partners move toward full serialization, aggregation of shipments, transmission of product identifier data, scanning of product identifiers, and inference of the contents of sealed containers, errors and exceptions may occur. For example, bar codes may not be readable, a trading partner may have products but no product data, or may have product data, but no products. As discussed above, aggregation may result in data errors where downstream trading partners have received legitimate product directly from the manufacturer or direct purchase distributor in the regular course of business, but have not received data with the product's identifier. With these issues arising during the Saleable Returns Pilot, HDA convened an Exceptions Handling Work Group through which manufacturer and wholesale distributor trading partners could begin to discuss business processes around handling these and other exceptions.

HDA believes exceptions handling could be an appropriate area for pilots. Mismatches between data and products and other errors in transactions between well-established trading partners do not necessarily indicate a product is “suspect” or “illegitimate.” Rather, any such mismatches are most likely due to human error, and technical “glitches” that inevitably will occur. Wholesale distributors and their trading partners are particularly eager to find ways to refine exceptions handling in order to quickly resolve these ordinary trading partner issues and keep important medicines moving to patients and healthcare providers. Pilots may help the supply chain develop more nuanced guidance and business processes that could minimize potential delays in product delivery and rationally address these mismatches while still maintaining robust systems for the identification and investigation of suspect products.

Interoperability

We addressed interoperability in our May 2016 comments and continue to believe in the utility of piloting interoperable electronic systems for seamless data exchange between two trading partners. In
order to develop pilots to test interoperability to meet 2023 requirements, HDA believes that the basic operational requirements for such a system must first be defined. In May 2016, we recommended, and continue to believe, that an interoperable system has the following attributes:

- Achieves DSCSA compliance,
- Allows two trading partners to seamlessly send and receive data,
- Is usable,
- Is highly secure,
- Is accessible only to the appropriate individuals and entities,
- Allows for trading partners to continue to efficiently meet existing “just in time” delivery deadlines,
- Is cost effective,
- Is reliable, and
- Has standardized data formats and clearly defined data elements in accordance with international standards.

**Additional Observations**

With respect to piloting potential interoperable systems, HDA has several additional observations.

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

Second, though HDA is reluctant to rule out any particular, potentially interoperable system, HDA’s current, and strongly held belief, is that a so-called “distributed” model for providing data between trading partners is preferable to a “centralized” or semi-centralized model. In the Saleable Returns Pilot, stakeholders did prefer a router service that directs each product identifier query to the appropriate manufacturer’s database for product identifier verification. A central depository holding all manufacturer product identifier information was deemed less desirable because of security, scalability and governance concerns, as well as other reasons. Stakeholders are now undertaking the laborious work of trying to develop a verification router service as none currently exists in the marketplace. However, we do not know if such a system, even if successfully deployed for returns verification, could be built out and scaled up to encompass the much greater data volume and other characteristics needed for satisfying the 2023 requirements.
Third, HDA believes achieving interoperability through a distributed system between two trading partners by 2023 is both possible and compliant with the DSCSA’s requirements. Trading partners, of course, might choose to test more complex interoperable systems and additional functionalities beyond the requirements of the DSCSA and we have no objection to such efforts. However, we caution that a successful pilot of an individual business process or interoperability may not be scalable (whether for technological, security or financial reasons) and would not necessarily be required for compliance even if it could be implemented as a practical matter.

Finally, HDA emphasizes that our experience has shown that a pilot may produce information that either confirms or changes “going in” expectations and anticipations regarding efficiencies, impacts, challenges and many other characteristics being studied. Thus, we urge maintaining an open mind about the possible alternatives and modifications that may need to be accepted and/or adopted based upon a pilot’s results.

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HDA thanks FDA for this opportunity to submit comments on the proposed DSCSA Pilot Project Program. If you have any questions or if HDA can provide further information that may be helpful, please do not hesitate to contact Anita Ducca, Senior Vice President, Regulatory Affairs, at 703-885-0240 or at aducca@hda.org.

Sincerely,

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