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RE: Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information. Dkt. No. FDA-2016-N-1114

Dear Doctor Jung:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information, [82 Fed. Reg. 19737 (April 28, 2017)], Dkt. No. FDA-2016-N-1114.

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.

HDA has previously submitted comments1 on Drug Supply Chain Security Act (DSCSA)-related pilots, and appreciates the opportunity to contribute to the docket again. The comments provided below are of a general nature. They are designed to share with the Agency what we know about the conduct of pilots to date, provide suggestions for what information FDA might see regarding pilots in the future, and to suggest how FDA might proceed in supporting pilot development over time or in conducting a pilot (or pilots) of their own.

PRIOR AND CURRENT PILOT ACTIVITIES

In HDA’s experience, and that of our members, pilots are initiated for a variety of reasons, including, but not limited to:

- learning, such as learning methods for integrating a compliance methodology/technology into existing business practices or to understand implementation challenges,
- proving out technology,
- onboarding trading partners,
- understanding the impact of potential errors, and
- gaining additional insight into operationalizing systems and processes.

Pilots conducted by supply chain members may or may not meet the specific requirements that the Agency has put forward, or are responsive to the information requested in prior Federal Register notices.

Importantly, so far, trading partners have prioritized their piloting efforts based on the DSCSA’s established timeline. Pilot activities are primarily taking place between manufacturers, distributors, and, in some instances, service providers looking into DSCSA specific requirements effective in 2017, 2018, 2019, and initial work on 2023. HDA members are currently operating numerous concurrent pilots both internally within a single company, and externally that involve additional trading partners, to explore various aspects of the DSCSA. There are also others being conducted through non-HDA organizations such as the Center for Supply Chain Studies or technology providers.

HDA is pleased to inform FDA of an example of a pilot for which planning is currently underway. This pilot is with regard to the HDA verification router service (VRS). As you know, the VRS is designed to aid in meeting the 2019 saleable returns requirement. A precursor of the VRS was one of the 2019 compliance methodologies included in HDA’s Saleable Returns Pilot.²

To explain further, HDA is currently organizing and preparing for industry end-to-end testing of the VRS. Over 30 test cases and scripts have been developed thus far in preparation for first round of testing anticipated for July/August and second round of testing in September/October of this year. To date, the work group managing this pilot has

- developed a messaging standard,
- initiated development of a Look-up Directory (LD) specification with targeted completion and review anticipated shortly,
- initiated registration criteria and a registration process for solution providers and users, and
- is coordinating with solution providers to develop technical details around the Look-up Directory.

As a result of these workstreams and the dynamic nature of discussions, we continue to refer back to our original business requirements and solution architecture documents to determine if they need updating. We will update documents as needed and continue to develop and publish them as they are completed. We anticipate communicating progress at regular intervals, presenting initial findings at the HDA Traceability Seminar³ in October, and publishing a written report at the end of the year.

² The HDA Saleable Returns Pilots, conducted in 2016, evaluated nine real-life scenarios or methods that could theoretically be employed to help meet the 2019 saleable returns requirements of the DSCSA. A verification router service was one of the two scenarios recommended to help pharmaceutical manufacturers and wholesale distributors comply with the DSCSA requirements. The HDA Saleable Returns Pilots Report is available online.
³ The HDA 2018 Traceability Seminar will be held October 17-19 in Washington, DC.
FUTURE PILOTS

HDA believes that many more pilots will be conducted in the future. One area we envision as likely suitable for a pilot, would involve data reconciliation processes and end-to-end supply chain pilots to help achieve 2023 compliance using aggregation and inference. HDA addressed these two areas in detail in its September 18, 2017 comments to docket No. FDA-2016-N-0407. We include additional points for consideration on these topics below.

Specifically, as HDA has previously explained, we believe that aggregation and inference are critical to the success of product traceability. Supply chain efficiency will be significantly aided by, and there is alignment among members of the supply chain that, DSCSA’s vision for 2023 is likely not possible without inference and aggregation. However, clearly, given the volume of products that flow through the supply chain, errors will occur.

To begin to develop options for managing the data reconciliation process when errors occur, HDA has convened an Exceptions Handling Work Group. This Work Group began by developing a list of possible exceptions, and then worked through a process to define and categorize them. The list of exceptions was provided to FDA.

As a next step, the Work Group plans to develop ways to address those scenarios in a consistent and standardized way. Concerted work to put together a more structured approach to address data and inference errors will not likely occur until 2019. Going forward, this work group will seek to quantify where in the process and how often errors might occur, as well as develop consensus on an approach to resolve them. HDA’s current judgment is that a pilot to aid in developing such consensus on resolution approaches will be beneficial. We intend to keep FDA informed of its future plans for developing such a pilot.

ADDITIONAL REMARKS AND RECOMMENDATIONS

As FDA continues to evaluate information on pilots it receives as well as its own role and responsibility in conducting and/or supporting pilots, we have the following additional observations and recommendations.

1. In our estimation, piloting jointly with downstream entities will be critically important. However, opportunities to do so will likely not happen on a large scale before 2020 because the emphasis in the short term is onboarding and ensuring connectivity between manufacturers and distributors and, for dispensers, meeting the requirements for transacting only in products bearing the identifiers. Even though pilot activities may not take place until later, HDA and its members are involved in concerted efforts to engage, educate and generally improve communication with dispensers. As FDA continues its own outreach to educate dispensers, we ask the Agency to encourage dispensers to participate in pilots, and even to define pilots on their own. FDA should also feel entirely confident that HDA would fully consider dispensers’ suggestions for future pilots, work with them on others we may jointly define, and/or refer them to HDA members who are seeking dispensers to participate in individual company pilots.

2. Second, there is also work underway currently that has the potential to be leveraged in support of meeting the 2023 requirements. While we do not yet know if a system such as the verification router service, 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, we currently believe it could

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4 See: HDA comments in Dkt. No. FDA-2016-N-2673 [81 Fed. Reg. 64175 (Sept. 19, 2016)]
5 Letter from Perry Fri, Executive Vice President Executive Vice President, Industry Relations, Membership and Education, and Chief Operating Officer, HDA Research Foundation to Connie T. Jung, R.Ph., PhD, Senior Advisor for Policy, Office of Drug Security, Integrity, and Recalls, OC, CDER; March 22, 2018.
serve to connect distributed databases. Technology is evolving, and we will continue to explore, and potentially consider pilots to test, options that allow for a system that is flexible, scalable, utilizes standards, and is highly secure that will work for all supply chain stakeholders.

3. Third, in instances where HDA members feel it would be valuable, they would like the opportunity to submit to the Agency for review pilot results and learnings on their own behalf or share the public reports of the pilots in which they participated. HDA also intends to submit any new learnings from our current iteration/plan review of saleable returns pilots (which may have lessons we can leverage for 2023) and will continue to explore other potential areas that may be appropriate for a future pilot. To facilitate the submission of findings and results, HDA suggests that the Agency keep this or another docket open, without specifying a closing date, so that submissions can be made on an ongoing basis and so that others considering pilots may benefit from, or avoid unnecessary duplication of, pilots that others have conducted.

4. Finally, we understand that FDA is looking into conducting a pilot or pilots of its own, potentially in conjunction with other parties, in order to meet the DSCSA’s directive for the Agency to conduct a pilot. We are curious as to the status of planning such a pilot by the Agency, its potential content and/or structure, and would appreciate an opportunity to view any information the Agency has available on its own pilot plans. Such information may help us as we, or our members, continue to consider potential pilots for the future.

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HDA thanks FDA for this opportunity to submit comments on Supply Chain Pilot Projects. If you have any questions or if HDA can provide further information that may be helpful, please do not hesitate to contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs