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Re: The Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information; Availability [79 Fed. Reg. 70878 (November 28, 2014)] [Docket No. FDA-2014-D-1981]

Dear Dr. Jung:

The Healthcare Distribution Management Association (HDMA) thanks you and the Food and Drug Administration (FDA) for the collective efforts on implementation of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA). On behalf of HDMA, this letter provides our views on FDA's draft guidance: *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information, Guidance for Industry* [79 Fed. Reg. 70878 (Nov. 28, 2014)] (Draft Guidance).

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated \$42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

HDMA thanks FDA for the timely issuance of the Draft Guidance. We thank FDA for its diligent and sincere efforts to achieve the DSCSA's goals of better securing the pharmaceutical supply chain, implementing product traceability, and achieving uniform licensure of wholesale distributors and third-party logistics providers, particularly given the DSCSA's stringent timetables.

Implementation of the DSCSA is requiring enormous effort by the pharmaceutical supply chain. HDMA members have found that the exchange of transaction information, transaction history and the transaction statement (TI, TH and TS) poses particular challenges. For example, because each supplier's system was designed individually and separately from that of other suppliers, the wholesale distributor must bring each supplier "on board" individually, on a company-by-company basis. By early-mid-December 2014, it was clear to HDMA members that the progress toward full DSCSA compliance for all trading partners for all transactions was not going to be complete by January 1, 2015. Thus, we also appreciate FDA's decision to exercise enforcement discretion until May 1, 2015 to give the supply chain time to achieve full compliance.

HDMA provides its comments below, but in summary:

- HDMA fully supports the Draft Guidance, and highlights several factors we urge the Agency to include in the Final Guidance.
- We offer a modest request for additional, clarifying language regarding the use of paper versus electronic systems.
- Our main concerns involve not what is in the Draft Guidance itself, but what still remains to be resolved. Thus, while we wish for FDA to address outstanding issues already presented to the Agency as quickly as possible, we also urge FDA to be cognizant of how significant changes to existing practices and systems already in use, or in development, may impact the pace of DSCSA implementation.

HDMA Supports the Draft Guidance

The Draft Guidance's approach is highly appropriate, particularly given the challenges the supply chain faces with the DSCSA's complex data provision requirements, the relatively short time frame for providing the data, and the extremely high volume of prescription drugs involved.

Specifically, FDA has avoided an overly prescriptive Draft Guidance. There are several features of the Draft Guidance we believe are particularly important to include in the Final Guidance without change from the Draft version. These include:

- The Draft Guidance focuses upon how supply chain trading partners can leverage existing systems to meet the DSCSA's product traceability goals. (*See, e.g.*, Draft Guidance at lines 166-67 "Trading partners can utilize current paper-based or electronic-based methods for the interoperable exchange of data"). Although we request that the Agency augment its discussion

of the use of paper-based systems as noted below, HDMA supports this practical, flexible approach.

- We also support the Draft Guidance’s explicit recognition of the multiple methods for the exchange of transaction data, including, but not limited to:
 - Paper or electronic invoices;
 - Paper packing slips;
 - Electronic Data Interchange (EDI) standards, such as the 856 Advance Ship Notice (ASN);
 - EPCIS (Electronic Product Code Information Services); and
 - Email or Web-based platforms (such as Web portals).

(Draft Guidance at lines 172-187).

- The Draft Guidance concentrates on describing initial standards (*see e.g.*, Draft Guidance at lines 33, 157) for the exchange of transaction data. HDMA agrees with the Agency that product traceability is a work of many years as the supply chain progresses, collectively and with FDA, toward full serialization and traceability. A start has been made, but there is much more to be done.
- We also understand and agree with FDA’s observation that, as standards and technologies mature, FDA may need to revisit the Draft Guidance. (Draft Guidance at lines 163-64).
- The DSCSA requires, by November 27, 2023, the establishment of an “interoperable, electronic” system for the tracing of certain pharmaceuticals at the package level. (Draft Guidance at lines 60-63); Federal Food, Drug and Cosmetic Act (FD&C Act), §582(g)(1), 21 U.S.C. §360eee-1(g)(1). The DSCSA does not define “interoperable.” FDA states that it “believes that ‘interoperability’ encompasses the ability to exchange product tracing information accurately, efficiently, and consistently among trading partners.” (Draft Guidance at lines 158-59). HDMA agrees with this definition.

HDMA Requests Clarifying Language Regarding the Use of Paper Versus Electronic Systems

Although HDMA supports paper-based systems for initial compliance efforts, HDMA does not believe that paper-based systems for the exchange of TI, TH and TS are anything but an interim, stop-gap measure. While we acknowledge that the DSCSA permits paper to satisfy TI, TH and TS requirements for the moment, paper nevertheless has significant limitations which make it infeasible as a long-term vehicle for data transmission:

- Paper is not “interoperable” as the Agency defines the term in the Draft Guidance;

- Accuracy and consistency, as well as storing and responding to verification requests, are far more challenging in paper-based systems than in electronic systems;
- Paper does not facilitate the efficient transfer of TI, TH and TS among trading partners; and
- Paper *is not* the “electronic” system the DSCSA ultimately requires.

Thus, we urge FDA to clarify two points in any Final Guidance the Agency issues and in other pronouncements. Clarifying these issues in the Final Guidance will aid trading partners in determining where their resources are best deployed to achieve DSCSA compliance within the statute’s timeframes.

First, the Final Guidance should clearly state that paper-based systems ultimately will not satisfy the DSCSA and that trading partners should adopt electronic systems as soon as possible. Second, we caution that email-based systems also do not meet the definition of “interoperable.”

We, therefore, suggest adding a footnote to the Guidance that states:

Although the DSCSA permits trading partners to exchange transaction data in paper formats, by November 27, 2023, an enhanced drug distribution security system goes into effect which requires interoperable, electronic tracing of product at the package level. [FD&C Act §582(g)(1)]. By then, paper-based systems for the tracing of product will not comply with the FD&C Act. Similarly, we do not believe that email-based systems meet the definition of “interoperable.” FDA urges trading partners to move away from paper-based and email-based systems as quickly as possible.

Where Further Guidance is Needed, HDMA Also Urges Cautious Consideration of the Potential Impact of Such Guidance

FDA states in the Draft Guidance that it may issue further guidance in the future, including how to “facilitate the interoperable exchange of product tracing information through standardization of data and documentation practices.” (Draft Guidance at lines 193-94). HDMA and other stakeholders, including the Pharmaceutical Distribution Security Alliance (PDSA), have urged FDA to clarify numerous issues. Collectively, stakeholders have provided comprehensive analyses and interpretations of the DSCSA’s requirements to FDA, as part of the supply chain’s implementation efforts and in recognition of the critical need for clarity. Such issues include, but are not limited to:

- DSCSA definitions of “manufacturer,” “co-licensed partner,” “authorized trading partner,” “transaction date” and “contact information;”

- Whether the abbreviated transaction statements trading partners are using will be acceptable; and
- What data elements trading partners need to exchange in certain transactions.

As reflected in their submissions to FDA, supply chain stakeholders have proceeded to build their DSCSA systems as best they are able based upon a good faith understanding of the statute and the realities of business practice. However, at this point, even what may be perceived as relatively small/inconsequential changes by FDA to practices adopted since the DSCSA's passage, may significantly impact operations and processes, including but not limited to:

- Revisions to data elements that must be identified and recorded, as well as revisions to arrangements for storing and exchanging these data;
- Revisions to written procedures;
- Retraining staff on new procedures;
- Retesting and verifying amended systems; and
- Trading partner revisions to procedures, data storage elements, and other systems and processes to assure consistency across supplier and customer systems.

At a minimum, if FDA ultimately issues guidance that is inconsistent with the practices and assumptions already embedded in existing systems, supply chain stakeholders will need the Agency to grant them time and enforcement discretion in order to implement the changes.

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HDMA thanks you for this opportunity to provide initial suggestions on the Agency's Draft Guidance pertaining to the exchange of transaction data. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs