HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

August 11, 2014

The Honorable Margaret A. Hamburg, M.D., Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: [Docket No. FDA-2014-D-0609] *Request for Comment on Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*

Dear Commissioner Hamburg:

On behalf of the Health Industry Distributors Association (HIDA), we appreciate the opportunity to provide comments in response to FDA-2014-D-0609 to inform the agency's efforts to implement the *Drug Supply Chain Security Act* (DSCSA, Public Law 113-54).

HIDA is the national trade association for medical surgical distributors. Our members deliver life-saving healthcare products to approximately 295,000 points of care including over 210,000 physician offices, 6,500 hospitals, 44,000 nursing home and extended care facilities. Each of our members is committed to promoting safety and savings throughout the healthcare supply chain.

HIDA commends the FDA for its outreach to the industry on the implementation of the DSCSA. We are committed to working with the agency and our trading partners to ensure a smooth transition to the new traceability requirements on January 1, 2015. The identification and disposition of "illegitimate products" in the supply chain is a key aspect of the DSCSA and provides important information for trading partners to utilize in their collaboration.

HIDA is a member of and supports the comments submitted by the Pharmaceutical Distribution Security Alliance (PDSA) on the Guidance. Specifically, we wish to reinforce the following:

- The scenarios identified by the agency that could increase the risk of suspect product entering the supply chain are overly broad; and
- Companies should be allowed to use existing systems and processes for identifying and evaluating suspect product as well as for notifying trading partners of illegitimate product.

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**Scenarios of increased risk for suspect product**

Many of the scenarios identified in the Guidance as presenting a significantly increased risk of entering the supply chain are overly broad. Useful insight from the FDA is important for the industry as preparations are underway to meet the January 1, 2015 deadline for the new traceability requirements. However, HIDA agrees with the PDSA comments that as currently drafted, the scenarios in the Guidance will likely cause undue concern and disruption within the distribution chain. For example:

- Purchasing product from a new source[1] should not typically increase the risk of a suspect product entering the distribution chain. To help ensure the legitimacy of businesses the DSCSA establishes a new requirement that all trading partners be appropriately licensed or "authorized."[2]
- The fact that a trading partner has been involved in business transactions where it sold or delivered suspect product[3] does not necessarily increase the risk of suspect product entering the distribution chain. "Suspect product" has not been determined to be illegitimate and may always be cleared.[4] In fact, the most diligent trading partners may be the most likely to identify suspect product, and that diligence should not cause such trading partners' transactions to be labeled as high-risk transactions.
- Similarly, not all products that have previously been the subject of an illegitimate product notification[5] should be deemed to increase the risk of suspect product entering the supply chain. Some limitations on this characterization should be included. For example, if a discrete quantity of a product is identified as illegitimate, all transactions involving that product should not be considered to present increased risk indefinitely. Some restrictions in time and circumstance should apply.
- Not all high-demand products[6] should be considered to present an increased risk of suspect product entering the distribution chain as a large number of products could be considered high-demand products. Unnecessarily identifying too broad a category of products as those that increase the risk of suspect product entering the supply chain may actually decrease the level of diligence given to those products that truly do present increased risk. Increased-risk characterization should be reserved for that small portion of products truly deserving of particular diligence.

[1] Draft Guidance, ln. 133.
[2] *See* FDCA §§ 582(b)(3), (c)(3), (d)(3), (e)(3).
[3] Draft Guidance, ln. 148–49.
[4] *See* FDCA §§ 582(b)(4)(A)(ii), (c)(4)(A)(ii), (d)(4)(A)(iii), (e)(4)(A)(ii).
[5] Draft Guidance, ln. 180.
[6] Draft Guidance, ln. 164.

- High-volume, low-value products[7] should not necessarily be considered a scenario that could significantly increase the risk of a suspect product entering the supply chain. This is a very broad category of products—high-volume, relatively low-priced products account for over 80% of the domestic prescription drug volume. Additionally, many high-volume products are of such low value there is no financial incentive for bad actors. In fact, Congress recognized the low risk presented by some high-volume, low-value products and expressly exempted those products from the traceability requirements of the DSCSA.[8]
- An incomplete transaction information, transaction history, or transaction statement[9] should not, in all circumstances, immediately be considered to increase the risk of a suspect product entering the supply chain. "Incomplete" information, for example, could be nothing more than a typographical error. Trading partners should have an opportunity—and, in fact, should be encouraged—to communicate and coordinate to correct incomplete transaction information, transaction history, and transaction statements to avoid unnecessary returns or misidentification of legitimate product as suspect.

**Allow use of existing systems and processes**

We appreciate and support the Agency's acknowledgement in the Guidance that trading partners may use existing systems and processes to terminate notifications.[10] HIDA strongly urges the agency to clarify in the final guidance that companies may use existing systems and processes to make initial notifications to trading partners.

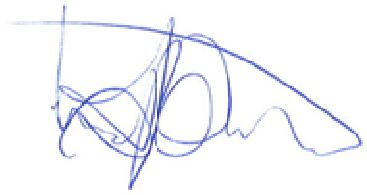
Most companies already have systems and processes in place to identify and evaluate product that may be illegitimate. The Guidance should afford trading partners the flexibility to use those existing systems and processes, and their related experiences, to determine on a case-by-case basis the best methods for identifying and evaluating suspect product.

Additionally, companies have effective systems and processes in place for notifying and communicating with trading partners about illegitimate products. These systems and processes are uniquely tailored to each company's operations and its relationship with their trading partners.

[7] Draft Guidance, ln. 169.
[8] *See, e.g.*, FDCA § 581(24)(B)(xiv)–(xvi).
[9] Draft Guidance, ln. 159–60.
[10] Draft Guidance, ln. 337–41.

HIDA appreciates the opportunity to provide comments on the FDA's *Request for Comment on Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.* Medical surgical distributors serve a unique role in the pharmaceutical supply chain and look forward to working with the FDA on implementation of DSCSA. If you need additional information please contact me at 703.838.6125 or rouse@hida.org.

Sincerely,



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