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BY ELECTRONIC MAIL

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Deputy Director, Program Operations
Office of Compliance
Food and Drug Administration
Room 5266, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Draft Guidance Development on Suspect and Illegitimate Product (Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA))

Dear Dr. Bernstein:

The Healthcare Distribution Management Association (HDMA) thanks you and the Food and Drug Administration (FDA) for the collective efforts to begin implementation of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA). One of FDA’s first requirements under the DSCSA is to promulgate draft guidance by May 26, 2014, to aid trading partners in identifying suspect and illegitimate product and in illegitimate product notification termination. See 21 U.S.C. § 360eee-1(h)(2).

HDMA is the national association representing primary wholesale 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 nearly 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.

As wholesale distributors receive, handle, store and distribute millions of products in the manufacturer’s final packaging every day, they have a unique, though limited, role in identifying suspect and illegitimate product. To aid in development of this draft guidance, HDMA offers below the perspective of primary wholesale distributors to explain what they can do, and are already doing, to prevent the distribution of suspect and illegitimate drugs in the United States.
Discussion

The DSCSA sets out, in 21 U.S.C. § 360eee-1(h)(2), the three elements FDA shall include in the draft guidance. HDMA first addresses below the general principles that we believe could be a useful foundation for FDA’s development of the draft guidance. Thereafter, HDMA offers the perspective of primary wholesale distributors on the three elements in 21 U.S.C. § 360eee-1(h)(2) that Congress instructed FDA to include in the draft guidance.

1. General principles

- Leverage processes already in place

Wholesale distributors currently have processes related to handling and notification of suspect products, and to support efficient and effective implementation of product recalls and market withdrawals. They work cooperatively with trading partners in these and other situations to help identify, quarantine and process products that are subject to recalls and market withdrawals. Wholesale distributors already have Standard Operating Procedures (SOPs) in place to facilitate actions pursuant to 21 C.F.R. Part 7 Subpart C, to provide requested reports to the recalling party, and to meet other federal and state requirements for managing product that may be unsuitable for distribution. We recommend that the draft guidance allow supply chain partners to leverage these existing processes and procedures in order to nimbly respond to similar situations, without adding operational complexity.

- Recognize the variability among supply chain partners

The pharmaceutical supply chain is large and varied, with different entities performing very different functions. Every day wholesale distributors receive thousands of prescription drugs in the manufacturer’s final packaging, from hundreds and even thousands of manufacturers; and, in turn, move those drugs, without damage and intact within their original containers, to tens of thousands of healthcare practitioners and dispensing sites. Dispensers, in turn, receive these packages of pills and solutions, open them, and dispense or administer the medicine to patients. Consequently, the SOPs that a primary distributor uses to define how to identify suspect product will necessarily be different than those for a dispenser or a manufacturer.

To accommodate these differences, we recommend that the draft guidance acknowledge the differences for each supply chain sector, e.g., manufacturer, wholesale distributor, dispenser, etc. We suggest that the draft guidance recommend that a supply chain member have SOPs that are appropriate, both for the sector in which it operates, and for its individual company business practices. The draft guidance could emphasize the importance of appropriate employee training and that a company’s SOPs need to be flexible in order to evolve with the dynamic pharmaceutical supply chain.
2. **21 U.S.C. § 360eee-1(h)(2)(i)—the draft guidance shall “identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain”**

- **Evaluate suppliers**

As discussed above, a single distribution center may handle thousands of prescription drugs per day purchased from many different manufacturers. The distributor is responsible for providing intact, unopened bottles and cartons to customers so that product is suitable for these customers to open and dispense/administer to their patients. Thus, at the primary distributor level, an effective deterrent to illegitimate product entering the pharmaceutical supply chain is to evaluate suppliers as part of the decision making process associated with instituting a business relationship with them. Having SOPs in place for assessing such factors as a potential new supplier’s corporate history and operational and financial stability before establishing a business relationship could aid in reducing the risk of ever acquiring an illegitimate product in the first place.

3. **21 U.S.C. § 360eee-1(h)(2)(ii)—the draft guidance shall “provide recommendation on how trading partners may identify such product and make a determination on whether the product is a suspect product as soon as practicable”**

- **HDMA urges focusing on maintaining robust SOPs**

HDMA suggests that the draft guidance focus upon recommendations that supply chain members have in place SOPs to respond to potential suspect product situations as described in the DSCSA. A flexible approach will likely be the best way to preserve supply chain security and reduce risks to patient health because no two suspect product situations are alike. We believe an FDA guidance that encourages supply chain members to maintain robust SOPs will be more likely to capture the variety of situations under which suspect products may occur. Moreover, a flexible approach, which we believe is achievable by maintaining SOPs, is more likely to support supply chain members’ efforts to prevent and respond to suspect product situations.

HDMA also believes that a draft guidance that emphasizes SOPs will foster greater supply chain security than will “check lists” and other alternatives that may be more prescriptive. A flexible, SOP-focused draft guidance could support suspect or illegitimate product identification in a manner that is less likely to inadvertently reveal how pharmaceutical supply chain members, regulators and law enforcement thwart counterfeiters’ efforts to introduce illegitimate products into the supply chain.

- **A product should not automatically be considered “suspect” because of incorrect data or a limited number of broken containers/damaged labels**

Wholesale distributors have significant experience with paper and electronic data exchanges with their manufacturer suppliers and dispenser customers. In the rare instances where data elements are
found to be missing or incorrect in these exchanges, such errors are nearly always quickly resolved by communication with the supplier. HDMA strongly urges that the draft guidance clarify that a product need not automatically be classified as “suspect” if there are incorrect data elements. The recipient should be permitted to contact its trading partner, and rectify such minor errors, prior to concluding whether a product is suspect.

In a similar vein, if a wholesale distributor occasionally receives a shipment that contains a limited number of damaged products, such as broken containers or torn labeling, we suggest that the draft guidance recognize that the shipment is not automatically suspect. Rather, the draft guidance should permit the recipient to develop and follow SOPs which recognize that the recipient can first take other logical and appropriate steps to resolve the situation, such as contacting the supplying trading partner.

HDMA believes that in both scenarios above, to do otherwise could result in sending distributors and other supply chain members into multiple and/or unnecessary and complex review processes that, rather than aiding in identifying truly suspect/illegitimate products, would encumber established and secure business practices and potentially delay patient care.

- **Wholesale distributors perform unique tasks which must include safeguarding the integrity of the product and its packaging**

As discussed above, wholesale distributors only handle products in the manufacturer’s final packaging in a rapid, high volume and highly automated system. Because wholesale distributors must maintain the integrity of the product, identifying suspect product will typically focus on the appearance of the packaging. Moreover, where “suspect” product is potentially in the supply chain, wholesale distributors typically identify it through notification by a supply chain partner or through another source, such as FDA’s Counterfeit Alert Network (CAN) notifications.

In the rare instances where a wholesale distributor receives a drug package that appears damaged or compromised, the problem is usually one that arose during shipment from a known supplier with whom the wholesale distributor has an established business relationship and is quickly resolved by the wholesale distributor contacting the supplier. HDMA suggests that the agency recognize these practicalities and incorporate them into the draft guidance.

- **The draft guidance should specify that wholesale distributors have SOPs to respond rapidly and appropriately to any “suspect” product notifications**

Wholesale distributors currently have SOPs for managing actions that necessitate identifying product in inventory and removing it from distribution. Key distributor responsibilities include: verification of the suspect product report with the notifying party; rapid dissemination of the report received; rapid quarantine of product for further examination; and providing notifications and handling product in accordance with received instructions. Such SOPs are appropriate given distributors’ roles as both product purchasers and product suppliers, and the number of suppliers, products, and customers a typical wholesale distributor services, sometimes through multiple
warehouse operations. HDMA suggests that the draft guidance recommend that wholesale distributors update existing SOPs to reflect the DSCSA’s requirements and address potentially “suspect” product.

4. 21 U.S.C. § 360eee-1(h)(2)(iii)—the draft guidance shall “set forth the process by which manufacturers, repackers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product…”

HDMA maintains that a rapid termination process for cleared product initially believed to be illegitimate is vital for patient health. Patients and prescribers need to have their confidence in needed medications restored quickly. To reduce the potential disruption to delivery of patient care, HDMA recommends that, at the outset, notifications of illegitimate product be as specific and clear as possible.

Additionally, assuming that a product previously designated as illegitimate is appropriately “cleared,” HDMA believes the draft guidance should clarify that termination notifications need only be disseminated to those who received the initial notification.

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HDMA thanks you for this opportunity to provide initial suggestions on the suspect and illegitimate product draft guidance. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,

Anita T. Ducca  
Vice President, Regulatory Affairs