August 11, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Food and Drug Administration (FDA) Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (Docket No. FDA-2014-D-0609)

The Pew Charitable Trusts – Supplemental Comment

We thank the U.S. Food and Drug Administration for the opportunity to provide comments on draft guidance for the identification of suspect pharmaceutical product and the associated process to notify affected supply chain stakeholders of illegitimate product – foundational elements of the Drug Supply Chain Security Act

The draft guidance covers a wide range of risk factors that companies should consider when screening for suspect product, including product sourcing, market signals, and product appearance. This breadth of scope in the guidance should be maintained. However the FDA should also add clarity to its recommendations to ensure supply chain sectors can meaningfully operationalize them, and should provide guidance to help stakeholders differentiate between scenarios of higher and lower risk.

In a separate comment we have provided five general recommendations on the draft guidance. This comment provides additional detailed recommendations by section to supplement the general recommendations.

Overview of general recommendations (please see separate comment for full discussion)

1. **Maintain breadth, but differentiate scenarios by level of risk:** FDA should differentiate scenarios by level of risk and identify distinct responses from industry supply chain stakeholders for each scenario. FDA should also add detail to more carefully define the characteristics of specific scenarios.
2. **Add specificity on handling incomplete transaction information:** FDA should include recommendations to industry supply chain stakeholders on how to address incomplete transaction information that may be due to inadvertent errors.
3. **Clarify validation of transaction history (chain of custody):** The FDA should identify and explain the steps industry supply chain stakeholders should take to validate transaction histories (chain of custody) when investigating suspect product.

4. **Include standard operating procedures to screen for suspect product:** FDA should recommend that companies develop and implement standard operating procedures for screening and designating a product as potentially suspect.
5. **Encourage proactive serial number checking as screen for suspect and illegitimate product:** FDA define best practices in guidance to not only allow industry supply chain stakeholders to comply with the law, but to also encourage proactive and possibly automated checks of unique serial numbers on individual packages of drug product at routine points of distribution throughout the supply chain.

RECOMMENDATIONS BY SECTION

Section III. Identification of Suspect Product

A. Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Chain

The draft guidance covers a wide range of risk factors that companies should consider when screening for suspect product. However, the specific scenarios listed in this section should receive additional detail to indicate how trading partners should respond. While the draft guidance says that trading partners should be "particularly diligent" it is unclear what steps they should take in each scenario to operationalize this expectation.

In some cases, product should be treated immediately as suspect and investigated per the requirements of the law. In other cases, interim steps would more reasonable to ascertain whether a product should be designated as suspect. More robust steps could be called for if more than one scenario applied to the transaction. Responses to specific scenarios are below.

1. Trading Partners and Product Sourcing

- Purchasing from a source new to the trading partner: Products purchased in such a scenario should not automatically be deemed suspect. FDA should outline potential steps for trading partners to increase their scrutiny of product from new sources. This could potentially include spot checking the transaction history, or spot checking serial numbers once in place.

- Receiving an unsolicited sales offer from an unknown source and purchasing on the Internet from an unknown source: If such product is purchased, additional diligence is warranted, such as checking the transaction history in every case, confirming source licensure, or checking all serial numbers in the initial shipments from these sources.

- Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products: This scenario includes several sub-scenarios described in the guidance that warrant different responses. If a trading partner is in a situation where they must

purchase from a source that has knowingly traded in suspect products, arguably such purchases should be treated as suspect, and quarantined and investigated before release. However if a trading partner only provides incomplete transaction information, this could be an inadvertent error with electronic data transmission. Guidance should specify that trading partners may identify and resolve these inadvertent errors expeditiously without necessarily entering into a full quarantine and investigation process for suspect products

- Section III-A-1 should also include a scenario listed in Section III-B — product that is for sale at a very low price or one that is "too good to be true" should trigger additional diligence, such as a spot check of the transaction history, or a spot check of serial numbers once in place.

2. Supply, Demand, History, and Value of the Product

- A number of the scenarios described in Section IIIA-2 of the draft guidance are common, and stakeholders may have no choice but to encounter them. These include product that is generally in high demand in the U.S. market; product that has a high sales volume or price in the United States; and product that has been previously or is currently the subject of a drug shortage. Products purchased in such scenarios should not automatically be deemed suspect. FDA should outline potential steps for trading partners to increase their scrutiny of these products when more than one scenario applies. This could potentially include spot checking the transaction history, or spot checking serial numbers once in place.

- In scenarios where a product has been or is currently counterfeited, diverted, or stolen, the increased diligence should be greater, but also may be different depending on whether the situation is in the past or in the present. Products under active illegitimate product notifications, or otherwise known to be currently counterfeited, stolen, or diverted should all be treated as suspect products upon receipt. Where theft, counterfeiting or diversion has occurred in the past, increased due diligence may be necessary, but the product should not automatically be deemed suspect in all circumstances.

3. Appearance of the Product

- In general, in any scenario where product tampering appears likely, the product should be immediately designated as suspect product, and quarantined and investigated.

B. Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

- Companies should take the initiative to look for suspect products, and should have standard operating procedures systems to ensure employees screen for suspect products. SOPs should

include set criteria to enable staff to decide whether a product is suspect and thus must be quarantined and investigated.

- Trading partners should also have processes to monitor information on issues such as theft and counterfeiting to support suspect product designation when product is received.
- Standard procedures should also include screening for hidden features applied to products at higher-risk for counterfeiting and diversion.

Section IV. Notification of Illegitimate Product

A. Notification to FDA

B. Termination of Notification in Consultation With FDA

- The proposed process should give the FDA sufficient control over the determination that a notification is no longer necessary. This determination, as stipulated by the law, should not be entirely at industry discretion.