



**American Pharmacists Association**<sup>®</sup>  
Improving medication use. Advancing patient care.

April 21, 2016

[Submitted electronically to <http://www.regulations.gov>]

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

**RE: Proposed Pilot Project(s) Under the Drug Supply Chain Security Act  
Docket No. FDA-2016-N-0407**

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide feedback on the Food and Drug Administration’s Public Workshop on Proposed Pilot Project(s) Under the Drug Supply Chain Security Act (DSCSA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with FDA and other health professionals and stakeholders to enhance the safety and security of the pharmaceutical distribution supply chain. APhA appreciates the Agency’s decision to seek stakeholder input at and in follow up to the public work shop. Because of the size of and variability amongst pharmacies, especially compared to other supply chain entities, APhA advocates that any new requirement stemming from these pilot project(s) should be able to be easily incorporated into existing pharmacy operating systems and workflow and at a minimal cost so as not to negatively impact patient care and services.

#### **I. Size of and variability amongst pharmacies**

As the health care professional who most frequently dispenses medications to patients, the pharmacist plays a vital role in protecting patients from illegitimate products. When designing the pilot project(s), APhA encourages FDA to consider the difference between pharmacies, the majority of which are small businesses, and other supply chain stakeholders, such as manufacturers and

wholesalers. Pilot(s) must also account for the variability amongst pharmacies, which vary in size, offerings and capabilities.

At the public workshop, FDA discussed potential components of the pilot(s) and implementation timeline. APhA has concerns that some of the aspects discussed would require advanced technological capabilities beyond or in advance of DSCSA requirements. Because of the variability amongst pharmacies, including differing business practices and technology capabilities, APhA recommends FDA notify and educate potential participants as early as possible and well in advance of implementation. APhA is willing to help FDA's outreach efforts to pharmacies by reviewing and disseminating dispenser-specific materials FDA develops.

Many pharmacies have contracted with third parties to comply with the DSCSA and thus, may not have direct control over the software and hardware used. Therefore, APhA recommends pilot project(s) include pharmacies using different compliance methods in order to provide a comprehensive view of existing strengths, weaknesses, opportunities and threats. APhA believes this will improve the applicability of the results and provide FDA with better data to inform decision-making and allocate resources aimed at securing the supply chain.

Finally, APhA has concerns regarding the timeline for the pilot(s). DSCSA compliance dates are staggered and because pharmacies are at the end of the supply chain, their compliance dates are later than those of other trading partners. For example, manufacturers and repackagers are required to place a unique identifier on certain prescription drug packages by 2017 and 2018, respectively, while wholesalers and dispensers have until 2019 and 2020, respectively, to meet their requirement to only accept products with identifiers. Consequently, dispensers may not have systems in place to participate in pilot project(s) involving product identifiers if pilots are implemented prior to 2020, and to do so would likely be burdensome and costly. Lastly, since several deadlines have already been delayed, FDA may consider re-evaluating the enforcement of current DSCSA deadlines and the impact delays would have on the timelines of the pilot project(s).

a. Interoperability

At the public workshop, significant time was spent discussing interoperability. Like other members of the supply chain, APhA believes that interoperable systems are essential to effectively tracking and tracing medications. A vulnerability in the supply chain may exist when systems are not interoperable or when information is not available or delayed. Pilot project(s) should consider existing technology capabilities, and the costs and time associated with implementing new systems or making changes for the varied supply chain stakeholders.

While APhA's membership has not expressed a preference for systems that enable serialized data exchange, such as the Electronic Product Code Information System (EPCIS), testing such systems is an inevitable component to securing the drug supply chain. As these systems are tested, we urge FDA to evaluate costs to dispensers, especially smaller and independent pharmacies that may find implementation more challenging/ cost-prohibitive. APhA is concerned that if systems are implemented that are not interoperable with existing pharmacy systems, then trading partners will stop or limit transactions with pharmacies that cannot readily adopt serialized data exchange systems, increasing costs, limiting patient access and potentially driving dispensers out of business.

## b. Identifying suspect / illegitimate products

Although pharmacists are on alert for fraudulent medicines, little training or information is available to pharmacists to help them detect such products. We appreciate FDA's draft guidance regarding identification of suspect products<sup>1</sup>; however, our members have expressed the need for more education on the identification and determination of illegitimate products in order to best protect the integrity of the supply chain. In addition, APhA suggests that FDA's pilot project(s) include a standardized electronic process that simultaneously notifies both FDA and immediate trading partners. We believe that FDA Form 3911 could be enhanced to allow a notifying party identify the immediate trading partner, and through a streamlined electronic notification process, FDA and immediate trading partners could contemporaneously receive standardized relevant information about the quarantined product. FDA's development of this single standardized form could decrease the time it takes trading partners to notify, thus minimizing interruptions in the delivery of patient care and facilitating compliance with the 24-hour notification time mandate.

At the workshop, many stakeholders were interested in pilot project(s) involving aggregation, disaggregation and inference. Because inference allows for the replacement of item-level tracking with aggregate-level tracking, it limits the need to open and scan pallets, totes, and cases manually as they move through the supply chain until individually scanned by the pharmacist. APhA believes FDA needs to test the impact of aggregation, disaggregation and inference on safety and security in the pilot project(s) and any error or validation methods, including suspect / illegitimate product identification, should be able to be easily incorporated into the pharmacist's work flow without excessive cost or resources.

## II. **Inclusion of varied stakeholders**

APhA members participating in track and trace projects administered by private entities have noted these pilots limit secondary wholesalers that they may buy from because such wholesalers cannot meet the system requirements of the pilot. As a result, dispensers have fewer buying options. Thus, APhA suggests that FDA's pilot project(s) consider existing stakeholder capabilities and whether dispensers' buying options would be unnecessarily limited as this could ultimately impact patients by increasing costs for pharmacists.

In addition, APhA members noted that many independent pharmacies participate in cooperative buying groups which, among other benefits, have helped pharmacies comply with DSCSA. APhA encourages FDA to gain additional feedback from these stakeholders that appeared underrepresented at the workshop and include these entities in pilot project(s) as they may be better positioned to engage in pilot project(s) with small or independent pharmacies.

## III. **Returns and drop shipments**

As with many other supply chain stakeholders, APhA agrees that FDA's pilot project(s) should examine the safety and security of drop shipments and returns.

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<sup>1</sup> See, Food and Drug Administration (2014). *Guidance for industry: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (Draft Guidance)*, available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf>, last accessed: April 20, 2016.

#### **IV. Use of information**

Given the type and amount of data that is being transferred through DSCSA and the proposed pilot project(s), our members believe that this data could be useful in assessing pharmacy services and making improvements to benefit patients. APhA supports pilot project(s) that evaluate how to best capture and access DSCSA-related data.

#### **V. Dispenser transfers without a wholesale distribution license**

There is significant confusion regarding whether a dispenser requires a wholesale distribution license for transfers between pharmacies without a specific patient need under FDA's existing guidance and regulations. Numerous pharmacies, especially independent pharmacies, rely on dispenser-to-dispenser transfers to provide patient access to medications. Given the importance of these transfers to patients and pharmacies, APhA urges FDA to consider pilot project(s) that test different dispenser-to-dispenser transfers to assess the scope, frequency and actual risk these transfers pose to the safety and security of the supply chain.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with FDA to test pilot project(s) that aim to improve the safety and security of the drug supply chain using practical and feasible implementation approaches. If you have any questions please contact, Jenna Ventresca, Associate Director for Health Policy, by email [jventresca@aphanet.org](mailto:jventresca@aphanet.org) or phone (202) 558-2727.

Sincerely,



Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA  
Executive Vice President and CEO