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APhA

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

RE: Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information
Docket No. FDA-2016-N-1114

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to provide a response to the Food & Drug Administration's ("FDA") Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information ("RFI"). 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 efforts to seek stakeholder input, including hosting the April 2016 Public Workshop. 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. In addition, APhA urges FDA to strengthen education efforts that target pharmacies to improve compliance efforts and limit vulnerabilities within the supply chain.

I. Pharmacist education

As FDA moves forward in implementing DSCSA, APhA urges the Agency to increase educational outreach efforts to pharmacies. Despite efforts by APhA and other pharmacy organizations to inform pharmacists about DSCSA requirements and compliance, APhA remains concerned that there needs to be better awareness. Unlike most of the other participants in the supply

chain, pharmacies are smaller and do not have the legal resources to devote to DSCSA implementation and therefore, are more likely to need and rely upon government informational materials and education. Moreover, for outreach targeted to pharmacies and pharmacists to be successful, it needs to be robust due to the fact that the number of pharmacists and pharmacies far exceeds that of other categories of supply chain entities (e.g. manufacturers). Many of our members indicated that they rely on wholesalers for DSCSA compliance and education because there is a lack of FDA-developed DSCSA-related resources targeted to pharmacies. In fact, APhA members indicated that they were unaware that FDA is exploring pilot projects and stated that their participation in such projects highly unlikely, often because of resource constraints or concern over interrupted workflow. While APhA will continue to educate its pharmacist members on DSCSA implementation, we believe that FDA involvement would increase awareness and improve message consistency, ultimately advancing compliance and the safety and security of the supply chain. APhA is willing to help FDA's outreach efforts to pharmacies by reviewing and disseminating dispenser-specific materials FDA develops.

II. Variability amongst pharmacies

As the member of the supply chain who most frequently dispenses medications to patients, the pharmacist plays a vital role in protecting patients from illegitimate products. While it may be clear that there are substantial variances between pharmacies and other members of the supply chain, other differences, such as size, resources, patients and business practices, including DSCSA compliance methods, exist amongst pharmacies. When designing pilot project(s), APhA encourages FDA to consider the diversity between pharmacies, the majority of which are small businesses, and other supply chain stakeholders, such as manufacturers and wholesalers. Pilot project(s) should include a wide range of pharmacies and evaluate projects with consideration of the pharmacy's characteristics.

As APhA noted earlier this year[1], pharmacy participation could be limited because pilots may require technological capabilities beyond or in advance of DSCSA requirements. New or earlier technology requirements can be particularly onerous on smaller pharmacies. It is important that pilots include a wide range of pharmacy practices to test 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 to gain meaningful pharmacy participation that is representative of the current supply chain environment.

Many pharmacies have contracted with third parties or rely on wholesalers to comply with DSCSA and thus, may not have direct control over the software and/ or hardware used. Therefore, a pharmacy may not possess or be able to purchase or implement the technology to utilize the product identifier – an anticipated component of the pilot project(s). In order to provide a comprehensive view of existing strengths, weaknesses, opportunities and threats, APhA recommends that pilot project(s) include pharmacies using different compliance methods. APhA believes this will improve the applicability of the results and provide FDA with better data to inform decision-making, including those pertaining to resource allocation and supply chain security.

APhA also has concerns regarding the timeline for the pilot project(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,

[1] *See* American Pharmacists Association comment letter submitted to Docket No. FDA-N-0407.

while wholesalers and dispensers have until 2019 and 2020, respectively, to meet the 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. Furthermore, 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

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. 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 small and independent pharmacies that may find implementation more challenging or 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. Rural pharmacies that lack or have slow internet connections are especially vulnerable to such exclusion from trading partners. Therefore, FDA's pilot project(s) also need to consider pharmacies' ability to achieve interoperability and mechanisms to optimize communication between stakeholders.

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[2]; 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. Thus, APhA encourages FDA to educate pharmacists on the identification and reporting of illegitimate products.

In addition to increased education, 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 notifying through a streamlined and standardized electronic process, all necessary stakeholders, including the FDA. 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.

[2] *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.

The RFI seeks information about the use of aggregation 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 and inference on safety and security in the pilot project(s). Additionally, error or validation methods, including suspect / illegitimate product identification, should be easy to incorporate into the pharmacist's work flow without excessive cost or resources.

III. Inclusion of varied stakeholders

APhA members participating in track and trace projects administered by private entities have noted that such projects have limited the pharmacy's choice of secondary wholesalers because some wholesalers cannot meet the system requirements of the pilot. In addition, pharmacists have noted that their choice of wholesalers is further narrowed because some pharmacies have to select wholesalers who have additional services related to DSCSA compliance. As a result of both pilot projects and compliance practices, dispensers have fewer buying options which ultimately affects costs to patients and their health care system generally. Thus, APhA suggests that FDA's pilot project(s) consider existing stakeholder capabilities and whether DSCSA is unnecessarily restricting buying options.

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.

IV. 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.

V. 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.

VI. 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 FDA's efforts and working 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 or phone (202) 558-2727.

Sincerely,

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Executive Vice President and CEO