AMERICAN PHARMACISTS ASSOCIATION
Improving medication use. Advancing patient care.

September 18, 2017

[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: Pilot Project Program Under the Drug Supply Chain Security Act; Request for Comments; Docket No. FDA-2016-N-0407

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to provide a response to the Food & Drug Administration's ("FDA") Pilot Project Program Under the Drug Supply Chain Security Act (DSCSA); Request for Comments ("RFC"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 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 is pleased FDA included some feedback from our previous comment letters and comments by participants from the April 2016 public workshop on pilot projects in the RFC. However, APhA still has concerns dispensers' voluntary participation in pilot projects will be limited based upon the content of the RFC, as described below.

I. Clarify Process

The RFC states FDA will seek pilot project participants and notes the Agency expects participants will propose the design and execution of their pilot project to FDA. As a result, it is not clear whether FDA will be soliciting and selecting individual entities to participate in pilot projects, or if groups of supply chain members must gather independently. If the latter option is FDA's intent, APhA is concerned only those entities most engaged in DSCSA implementation currently will be represented in the pilot project. As a result, the findings from the pilot project(s) may not accurately reflect the current environment because they will not likely include supply chain members with fewer resources, less sophisticated compliance methods, or not as closely

connected with other trading partners. Consequently, APhA recommends FDA employ a recruitment process that ensures the inclusion of a greater variety of supply chain members, which may include offering additional resources to those entities who do not have the means to participate.

In addition, APhA believes the process to develop pilot projects can be enhanced by gathering input from different members of the supply chain as soon as possible, in advance of finalizing pilot project development. While APhA recognizes the difficultly and time burden in posting each pilot project for public comment, we encourage FDA to consider methods to gain input from different members of the supply chain in advance of each pilot project implementation. Such a method could include developing and publishing a repository of information related to each stage of the pilot projects. The repository would include information before and after pilot project development and implementation to increase transparency, avoid duplicative efforts and help stakeholders track pilot projects.

II. Scope of Products in Pilot Projects

APhA is concerned the scope of the Pilot Project Program may deviate from the purpose of DSCSA. The RFC notes products eligible for proposed pilot projects may including any prescription drug product but FDA may also consider including product types outside the scope of "product" as defined in DSCSA, such as over-the-counter medications. While APhA appreciates the fact that supply chain security enhancements resulting from DSCSA may be reproducible in other contexts, we believe it is premature to pilot such applications in the midst of DSCSA implementation. APhA believes the requirement for FDA to establish pilot projects was to help DSCSA implementation efforts. If FDA is expanding the scope of pilot projects to apply advancements in supply chain security for additional products, then we believe the timeline for pilot projects would need to be delayed beyond 2023 to allow sufficient time for supply chain participants to adjust to the needs of these expanded pilots. Therefore, APhA recommends FDA limit the scope of products in pilot projects to those that fall within the meaning of section 581(13) of the Food, Drug & Cosmetic Act.

III. Interoperability

While APhA agrees with FDA and other members of the supply chain that interoperability is an important issue to examine in a pilot project, we offer recommendations to enhance the evaluation methods referenced in the RFC. As noted in the RFC, potential evaluation methods include time implications, capability to retrieve information and accuracy of the information within and between systems, among others. However, these methods appear to focus solely on outcomes and do not assess the steps needed to achieve interoperability from a practical perspective. APhA recommends FDA's evaluation methods include time to resolve data issues, training needs, and the impact of variable trading partners' systems and compliance solutions.

In addition to interoperability within and between systems, APhA believes interoperability between supply chain systems and government agencies' systems could be tested within the Pilot Project Program, which is consistent with the intent of the law to improve the safety and security of the supply chain. One area that could be tested is the efficiency of recalls.

IV. Funding

The RFC makes clear supply chain participants must self-fund pilot projects by stating "[t]he partners in any pilot project that is selected into the program will be responsible for the funding and resources necessary to conduct the pilot project, and for determining each partner's role and responsibility in the pilot project." However, in the RFC, FDA recognizes the importance of considering "a diverse set of supply chain stakeholders (types and sizes)". APhA believes FDA's desire to have participants self-fund pilot projects conflicts with the need to include a diverse set of supply chain stakeholders because some supply chain stakeholders do not have the staff and/ or financial resources to participate in a pilot project, which may require system and process changes. APhA urges FDA to consider funding pilot projects or requiring pilots to be structured in a manner that does not preclude participation due to cost.

V. Awareness

The RFC does not indicate how it will make members of the supply chain aware of the Pilot Project Program. APhA has consistently requested FDA perform dispenser-specific outreach to increase their education and awareness of the law. Because dispensers have the latest compliance deadlines, they generally must follow, rather than dictate, key compliance decisions that other members of the supply chain have made. Yet, issues associated with new DSCSA processes may often be realized at the dispenser level. To better educate dispensers and spur engagement in pilot projects, APhA encourages FDA to publish and promote dispenser-specific content with general information about the Pilot Project Program and DSCSA. Content regarding pilot projects should seek dispensers' participation in pilot projects and make clear anticipated costs, workflow issues and benefits of participation.

VI. General Education

APhA urges the Agency to increase educational outreach efforts to pharmacies on DSCSA requirements and implementation activities. Despite efforts by APhA and other pharmacy organizations to inform pharmacists about DSCSA requirements and compliance, APhA remains concerned their awareness is limited. Unlike most of the other participants in the supply chain, pharmacies are generally 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. While APhA will continue to educate its pharmacist members on DSCSA implementation, we believe 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.

VII. 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. As APhA noted earlier this year[1], pharmacy participation could be limited because pilots may

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

require technological capabilities beyond or in advance of DSCSA requirements. New or earlier technology requirements can be particularly onerous on smaller pharmacies. APhA reiterates the importance of these pilots including a wide range of pharmacy practices to test the variability amongst pharmacies, including differing business practices and technology capabilities. As previously noted, while FDA seeks a wide range of participants, the RFC does not include information as to how FDA will ensure a wide range of supply chain members actually participate in the Pilot Project Program.

Further demonstrating the need to include variable pharmacies is the fact that many pharmacies are relying on solution vendors or wholesalers to comply with DSCSA and thus, may not have direct control over the software and/ or hardware used. Therefore, it may be impractical (e.g., financial, staff, incompatible compliance solutions) for a pharmacy to possess, purchase, or implement specific technologies to utilize the product identifier in advance of the DSCSA dispenser deadlines. In order to provide a comprehensive view of existing strengths, weaknesses, opportunities and threats, APhA recommends pilot project(s) must include pharmacies using different compliance methods and potentially include solutions providers in the planning and execution of pilot projects.

VIII. Dispenser Transfers Without a Wholesale Distribution License

In recently released draft guidance, FDA clarified dispensers providing medications to another dispenser without a specific patient need would also be considered wholesale distributors. 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 piloting 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. Since FDA has yet to release guidance regarding exceptions and exemptions to FDA, APhA believes such data could inform FDA's decisions regarding exceptions and exemption in these circumstances.

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, Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

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

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs