



February 1, 2018

[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: December 5-6 Public Meeting: Enhanced Drug Distribution Security under the Drug Supply Chain Security Act

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide a response to the Food & Drug Administration’s (“FDA”) December 5-6 Public Meeting: Enhanced Drug Distribution Security under the Drug Supply Chain Security Act (hereinafter “Public Meeting”). 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. At the Public Meeting, discussions revolved around electronic interoperability, standards for data exchange, data architecture and potential resources and standards that could be utilized when implementing DSCSA. In addition, presentations at the public meeting provided an introduction to new technologies, such as block chain, that may be applied when complying with different components of DSCSA. However, the feasibility of implementing new technology adoption remain to be seen, especially at the pharmacy level. Unfortunately, pharmacies, especially small and independent pharmacies, lack the resources to test or research compliance solutions. Therefore, APhA strongly encourages FDA to advance pilot projects and work with other members of the supply chain to consolidate findings from other pilot projects to identify solutions and their potential impacts on different types and sizes of supply chain entities.

Lastly, as the final mandated DSCSA public meeting approaches, APhA encourages FDA to identify tangible steps the agency will take in response to information gleaned from the past two meetings and to provide more detailed information regarding the agency’s plans and work flow. Significant time was spent discussing the vision members of the supply chain have regarding DSCSA, but it remains unclear whether and how FDA will reconcile supply chain

members', including pharmacies, and agency perspectives. APhA encourages FDA to more clearly describe the agency's vision and expectation of the pharmaceutical distribution supply chain such that agreement may be attained with regard to each stakeholder's roles and responsibilities.

APhA appreciates FDA's efforts to secure the drug supply chain by facilitating public meetings to improve implementation of DSCSA. APhA looks forward to FDA's February public meeting and encourages FDA to maintain communication with members of the supply as implementation progresses. Thank you for your leadership 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, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

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