American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

August 8, 2014

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

[Submitted electronically to: www.regulations.gov]

RE: Drug Supply Chain Security Act Implementation; Identification of Suspect Product and Notification [Docket No. FDA–2014–D–0609]

Dear Sir/Madam:

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, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

I. Introduction

APhA would like to thank FDA for the opportunity to offer comments on this draft guidance, which we view as an important step in implementing the Drug Supply Chain Security Act (DSCSA). Patient safety is a chief concern for APhA, and we believe that taking steps to build a more robust supply chain will benefit the overall health and safety of the millions of patients that our members serve daily.

While APhA recognizes the importance of industry guidance that furthers patient safety, it is important to also consider the impact such requirements can have on patient care. Pharmacists are committed to patient safety and care, but when finalizing DSCSA-related guidance and regulation, we ask that FDA consider the amount of time pharmacists will spend on regulatory compliance and the impact that can have on patient access and cost. This is especially true at a time when there is an increasing public health need for pharmacists to help close the gap in primary care due to provider shortages by offering patient care services (e.g., immunizations, care coordination, disease state management). Given the heavy demands on pharmacy staff members, any new regulatory requirements must be weighed against the possible impact on patient care delivery. While APhA generally agrees that pharmacies should develop processes to inspect, quarantine, and notify FDA and

immediate trading partners of *suspect* product, pharmacies should not be required to develop processes to investigate and make the determination of whether a suspect product is illegitimate.

II. APhA Agrees with FDA that Supply Chain Participants Inspect, Quarantine and Notify

While APhA agrees with FDA that pharmacies should develop processes to inspect, quarantine, and notify FDA and immediate trading partners, we would like clarity on what pharmacies should do with suspect product once it is quarantined. The draft guidance is unclear regarding whether, following a determination that a suspect product is *legitimate*, a pharmacy should place the product into its regular inventory or whether the product should not be re-shelved and other protocols should be followed. Further, the draft guidance is unclear regarding if, after the determination is made that the suspect product is *illegitimate*, a pharmacy should ship the product to FDA or other government agency for further investigation. If the product must be sent to FDA or another agency, or is otherwise removed from a pharmacy's possession or control, we suggest that there be a process to reimburse the pharmacy for the cost of the product as well as any shipping and handling costs.

III. APhA Suggests a Streamlined Process for Notifying Immediate Trading Partners

In response to the statutory requirement that trading partners notify both FDA and immediate trading partners of illegitimate product within 24 hours, APhA suggests that FDA develop a standardized electronic process that simultaneously notifies both FDA and immediate trading partners. APhA appreciates the process developed for notifying FDA whereby a trading partner may submit information related to an illegitimate product on FDA Form 3911 and submit the form online. 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 will contemporaneously receive standardized relevant information about the quarantined product. FDA's development of this single standardized form will 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. This streamlined process will also standardize the information being shared which lends to better usability of the data, including tracking and analysis.

IV. APhA Believes the Statutorily Prescribed Investigative and Determinative Requirements Do Not Apply to Pharmacists/ Pharmacies

APhA believes that the DQSA does not mandate pharmacists/ pharmacies to comply with the investigative and determinative requirements. Pursuant to section 582 of the FD&C Act, trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA, to quarantine suspect product and promptly conduct an investigation, in

coordination with other trading partners, *as applicable*, to determine whether a suspect product is illegitimate. It appears from the statute, the pharmacy's duty to conduct an investigation and make a determination regarding illegitimacy could be satisfied when the pharmacy works "in coordination with other trading partners." In addition, the "as applicable" language appears to give even greater flexibility regarding imposing investigation and determination requirements.

Pharmacists are trained as medication experts, but not on how to properly determine whether a product is illegitimate, which cannot always be done with the naked eye. Requiring pharmacies to make this determination without leveraging the expertise and resources of immediate trading partners may be an additional public health concern. Therefore, APhA believes that the pharmacy's duty to investigate and determine whether a suspect product is illegitimate is satisfied when the pharmacy notifies FDA and immediate trading partners of the existence of the suspect product and provides information as needed during FDA and other non-pharmacy trading partners' investigations. This not only meets the statutory requirements but it is rational that government agencies with officials who are specially trained and entities that deal with the threat of illegitimate product entering their facilities at a higher frequency than pharmacies are best-suited to make these important determinations.

Thank you for the opportunity to provide comments on this important issue. We look forward to continue working with FDA and other stakeholders in implementing the DSCSA. If you have any questions or require additional information, please contact Michael H. Ghobrial, PharmD, JD, Associate Director, Health Policy, at mghobrial@aphanet.org or by phone at (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