October 23, 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RE: Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry (FDA-2017-D-1956-004)

Dear Sir/Madam:

The American Pharmacists Association ("APhA") and the National Community Pharmacists Association ("NCPA") appreciate the opportunity to provide a response to the Food & Drug Administration's ("FDA") Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry ("Draft Guidance"). 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. NCPA represents the interests of America's community pharmacists, including the owners of more the 22,000 independent community pharmacies. Together they represent an $80 billion health care marketplace and employ more than 250,000 individuals on a full and part-time basis.

APhA and NCPA are committed to working with FDA and other health professionals and stakeholders to enhance the safety and security of the pharmaceutical distribution supply chain. APhA and NCPA are pleased FDA provided clarity indicating pharmacies do not need to obtain a wholesale distributor license for specific patient need transactions. However, APhA and NCPA have recommendations and concerns related to the Draft Guidance as noted below.

I. Dispenser Transactions for a Specific Patient Need

Table 1 of the Draft Guidance provides that entities generally not included as a wholesale distributor include dispensers engaging in transactions for a specific patient need. APhA and NCPA appreciate this distinction as we believe it complements the exemption in Section 582(d)

of the FD&C Act which exempts dispensers from having to pass product tracing information to another dispenser when fulfilling a specific patient need. Our organizations understand that the overall intent of the specific patient need provision was to exempt dispensers from having to exchange product tracing information and adhere to wholesale distributor requirements, such as licensure. This exemption ultimately provides an important safeguard to patients' access to medication while also protecting the safety and security of the supply chain.

However, we are aware of several states that are requiring dispensers to register as wholesale distributors for specific patient need transactions. These requirements usurp protections provided by DSCSA and are inconsistent with the position noted in the Draft Guidance. Therefore, we recommend that FDA educate and clarify with state entities that dispensers are not required by the DSCSA to obtain a wholesale distributor license for specific patient need transfers between dispensers.

II. Documenting Specific Patient Need Transactions

APhA and NCPA appreciate FDA's efforts to secure the drug supply chain by recommending pharmacies document specific patient need transfers in a manner that would facilitate appropriate actions by the pharmacy in the event of an investigation of suspect or illegitimate product, recall, or notification of illegitimate product. We are concerned FDA's documentation recommendation may confuse dispensers because it is not clear what the FDA expects the sending and receiving pharmacies to document (if not the tracing information) to facilitate appropriate actions in the event of an investigation, recall, or illegitimate product notification. As a result, dispensers may interpret the Draft Guidance to mean that they must provide tracing information to comply with other parts of the law. This will create confusion given the exemption for specific patient need transactions. In addition, document requirements may not be reasonable because it may be difficult for dispensers to seamlessly share information stored with a third party. Consequently, APhA and NCPA suggest that FDA revise this statement to clarify that providing tracing information is not required and provide examples of information that dispensers may consider documenting.

III. Transaction Exemptions

APhA and NCPA urge FDA to provide additional clarification regarding exemptions to the term "transaction" in the Draft Guidance. APhA and NCAP are aware of confusion related to exemptions concerning public health emergencies and minimal quantities by a licensed pharmacist to a licensed practitioner. Because these exemptions are vague, many dispensers have stopped or are hesitant to engage in these transactions, out of fear of noncompliance. This negatively impacts patient access to needed medications. While APhA and NCPA are not requesting a strict interpretation of each exemption, we recommend that FDA provide multiple scenarios for each exemption to help dispensers comply with the law and continue to engage in exempt transactions to help patients access needed medications in these limited circumstances.

Related to exemptions for transactions, APhA and NCPA anticipate drug shortages in Puerto Rico and across the rest of the United States as a result of Hurricane Maria. As FDA is aware, Hurricane Maria caused significant damage and power interruptions to drug manufacturers that will result in drug shortages in the United States. However, it remains unclear

how FDA will handle drugs impacted by Hurricane Maria, such as those that were manufactured or otherwise involved in transactions in Puerto Rico during the public health emergency, which remain in commerce after the emergency.

Lastly, APhA and NCPA also request clarification regarding the exemption related to minimal quantities of medications for office use. Our organizations are aware of health care practitioners requesting minimal quantities of medications (i.e., vaccines) for administration in non-traditional care settings such as schools and places of employment. Consequently, APhA and NCPA request that FDA confirm "office use" may include variable settings and is not limited to a physician's office.

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, Health Policy, American Pharmacists Association by email jventresca@aphanet.org or phone (202) 558-2727 or Kala Shankle, Director, Policy and Regulatory Affairs, National Community Pharmacists Association by email kala.shankle@ncpanet.org or phone (703) 683-1178.

Sincerely,

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cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs, American Pharmacists Association, and Susan Pilch, Vice President, Policy and Regulatory Affairs, National Community Pharmacists Association