

June 22, 2015

Dr. Ilisa Bernstein
Deputy Director, Office of Compliance
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 51, Rm 5271
Silver Spring, MD 20993-0002

Re: Drug Supply Chain Security Act Enforcement Discretion

Dear Dr. Bernstein:

On behalf of the National Community Pharmacists Association (NCPA), The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA), we are writing to share our concerns with the fast-approaching July 1 deadline for dispensers to comply with the transactional requirements under the Drug Supply Chain Security Act (DSCSA). NCPA represents the interests of America's community pharmacists, including the owners of nearly 23,000 independent community pharmacies, APhA represents more than 62,000 pharmacists, pharmacy students and pharmacy technicians who provide care across the entire spectrum of health care settings and NASPA represents all state pharmacy associations.

Since the enactment of the DSCSA in November of 2013, the undersigned organizations have engaged in an ongoing and robust educational campaign to inform our members of the laws' requirements and encourage communication with trading partners, namely wholesale distributors, to determine how transaction information will be distributed, and what contractual arrangements might be available to meet the statutory record retention requirements. However, according to a recent survey of NCPA's membership as well as feedback from APhA and NASPA members, it would seem as though additional outreach and education is needed. About half of the NCPA survey respondents have been in contact with their wholesale distributors to discuss how the transaction information would be provided, and an almost equal number reported being unaware of services that wholesalers are offering to maintain and store the information. Less than 15 percent have entered into contractual arrangements with their wholesalers.

Our organizations also have increased concerns with respect to secondary wholesale distributors. Roughly 83 percent of NCPA members report utilizing the services of secondary wholesalers when there are drug shortages or a patient has a specific need for a drug that may not be generally available from primary distributors. However, less than 20 percent of survey respondents reported being aware of services that secondary wholesalers are offering – if any – to maintain and store transaction information. In addition, we remain concerned that the DSCSA requires secondary distributors to provide dispensers lot number information in the required documentation, but does not mandate that the information be included in a single document. This is of great concern to dispensers, particularly in light of the fact that some secondary wholesalers have indicated that the only manner in which they plan to pass the lot number information is on the actual bottle of medication being sold to the pharmacy. In order to be able to comply with the

record retention requirement of the law and in order to respond to requests for information from the FDA, it is essential that pharmacies receive this information in a single document—whether in paper or electronic format.

The DSCSA statute envisioned a staggered implementation schedule to allow manufacturers and distributors to refine their systems and processes for several months before dispensers were required to have systems in place to receive and store transaction information. With the December, 2014 FDA enforcement discretion delaying enforcement of the product tracing requirements until May 1, 2015, this implementation timetable has been compressed. Our organizations remain concerned that despite the extensive efforts by pharmacy and wholesale distributor associations to educate dispensers, some trading partners will encounter challenges beyond their control, with the possible outcome of disruptions in the supply chain.

In order to forestall potential disruptions in the pharmaceutical supply chain, the undersigned organizations respectfully request that FDA utilize its enforcement discretion to delay the July 1 product tracing deadline for dispensers. Our members fully intend to continue intense, concerted efforts toward full compliance, but by exercising its enforcement authority, FDA would allow progress to continue while minimizing the risk of product shortages or disrupting patient access to prescription drugs. We greatly appreciate FDA's efforts to oversee DSCSA implementation, and are willing to meet with you or agency staff to further discuss this request and provide any assistance we can to ensure implementation proceeds smoothly.

Thank you for your leadership and consideration of this request. If you have any questions, please do not hesitate to use us as resources.

Sincerely,



B. Douglas Hoey, Pharmacist, MBA
Chief Executive Officer, National Community Pharmacists Association



Thomas E. Menighan, BSP Pharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO, American Pharmacists Association



Executive Vice President/CEO, NASPA