March 5, 2018

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

RE: Packaging, Storage, and Disposal Options to Enhance Opioid Safety-Exploring the Path Forward (Docket ID: FDA-2017-N-5897)

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates FDA's public workshop ("Public Workshop") and request for comments ("RFC") regarding packaging, storage and disposal options to enhance opioid safety. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 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, hospitals, long-term care facilities, community health centers, physician office practices, managed care organizations, hospice settings, and the uniformed services.

APhA supports legislative, regulatory, and private sector efforts to address our Nation's opioid epidemic as long as efforts to curb misuse and abuse are appropriately balanced with the legitimate needs of the millions of patients living with pain. APhA is committed to working with the Food & Drug Administration (FDA), and other federal agencies, Congress, state agencies and officials, health professionals and other stakeholders to identify methods and tools that help curb opioid misuse and abuse, such as providing accessible and appropriate packaging, storage, and disposal options for patients with acute and chronic pain.

I. Preventing Accidental Exposure

APhA agrees with the FDA that accidental exposure to opioids has led to misuse by the elderly and children. However, those populations are not the only ones who may be accidentally exposed to opioids. APhA recommends FDA carefully identify and consider patient characteristics, such as issues with dexterity or memory that increase their risk of accidental exposure, in addition to population categories such as children and the elderly.

Accidental exposure may also occur when a patient consumes counterfeit and illicit medication, which are commonly purchased through illegal online pharmacies. As FDA continues to implement the Drug Supply Chain Security Act (DSCSA), APhA encourages FDA to consider policy solutions to prevent patients from being exposed to harmful products purchased online.

II. Data and evaluation

1. Pre-market

During the Public Workshop, methods to obtain premarket data, including human factors testing and comparative testing, were mentioned when discussing the data needed to inform policy. APhA encourages robust pre-market research, including the human factors testing, so as to capture potential unintended consequences for patients and others at risk of accidental exposure.

III. Patient Interactions Regarding Packaging, Storage and Labeling

1. Packaging

As presented at the Public Workshop, FDA and some stakeholders are encouraging the use of different packaging methods, including blister packs and unit of use packaging to increase adherence and prevent diversion. However, state scope of practice laws, product and patient needs may preclude use of different packaging options. For example, several states limit pharmacists' authority to change a prescription quantity to align with unit of use packaging which creates a barrier for patients. APhA recognizes that different drug product packaging options may enhance patient care, but encourages FDA to establish policies, including working with stakeholders, which support the pharmacists' ability to select appropriate drug product packaging.

As FDA considers alternative packaging, we also encourage the agency to consider factors such as cost and storage within a pharmacy. Pharmacies often operate at tight margins and have limited storage space. New and more technologically advanced vials may pose storage and cost issues to pharmacies which can limit a pharmacy's ability to purchase and stock such vials. Alternatively, pharmacies may use more sophisticated dispensing systems which may not be compatible with new vial designs or labeling. APhA encourages FDA to also evaluate the feasibility of pharmacies utilizing innovative packaging options.

2. Storage

In obtaining member feedback, both pill dispensers and locking solutions were identified as minor, and possibly ineffective, barriers to prevent drug seekers from taking medications or the containers in which they are stored. Members were unaware of research identifying the most effective storage methods. In addition, our members indicated costs associated with storage solutions can be a patient barrier. Given these issues and the limited research regarding the effectiveness of different types of storage solutions, there is an opportunity for FDA to provide information that will enhance practitioner and patient understanding. APhA encourages FDA to summarize evidence-based effective practices in a patient-friendly manner in order for pharmacists and other practitioners to use to inform patients. If there is no research, APhA requests FDA and other agencies to support researching the effectiveness of different storage solutions when used in a real-world setting, including the impact on both patient access to the medication and the solutions' ability to limit access to other, unintended users.

Related to storage is disposal. Pharmacists play an important role in educating patients regarding disposal options. Our membership noted patients can be confused by what constitutes appropriate disposal. As more disposal solutions are coming to market and suggested by health care practitioners, it is important that messaging be consistent and simple. Also, the risks of disposal options should be made clear to patients as some may overestimate risks associated with certain forms of disposal. We encourage FDA to develop resources outlining the different ways or mechanisms to utilize to appropriately dispose of medications.

3. Labeling

As FDA contemplates labeling, APhA requests the agency better distinguish the type of labeling being included in new policies. For example, 21 CFR 201.56 provides the labeling requirements for prescription drugs, but prescription drug labeling may also be known as prescribing information, package insert, professional labeling, direction circular and package circular. Consequently, as labeling changes are discussed broadly, it is not clear which components of labeling FDA is intending to change.

While prescription drug labeling contains useful information, the contents of the labeling changes are not patient specific. When considering the relevant information needed to improve patient safety, APhA encourages FDA to support the inclusion of indications or diagnosis codes on prescriptions. Often, pharmacists will receive a prescription with little context regarding the patient's condition or circumstances. Pharmacists are medication experts on care teams and receive more medication-related education and training than any other health care professional. Adding the indication or diagnosis code to the prescription will enable the pharmacist to better evaluate the appropriateness of the prescribed drug or treatment and can augment the impact of appropriate and informative labeling.

IV. Additional matters for consideration

APhA appreciates the efforts of FDA to identify solutions to improve packaging, storage and labeling. At the Public Workshop, significant time was spent discussing how changes to these elements can increase medication adherence while decreasing accidental exposure or inappropriate use. APhA notes pharmacist-provided services are an additional effective method to improve patient care and indirectly limit diversion. Unlike many of the other elements contemplated at the Public Workshop, pharmacist-provided services, such as medication therapy management and appointment-based medication synchronization, are tailored to the patient. Currently, pharmacist provided-services are often not covered by payers, including Medicare, despite their benefit to patients or the system as a whole. APhA encourages FDA to work with other federal agencies to communicate the value of pharmacists in impacting patient safety and medication awareness

Thank you for the opportunity to provide comments in response to FDA's Public Workshop. APhA believes it is imperative that a proper balance be maintained in delivering appropriate pain management for the millions of patients with legitimate needs for opioids while taking steps to minimize and prevent misuse and abuse. As you move forward, please do not hesitate to use APhA as resource. If you have any questions or require additional information,

please contact Jenna Ventresca, Director, Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

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Executive Vice President and CEO

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