December 28, 2017

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

RE: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments (Docket ID: FDA-2017-N-5608-0001)

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the Food & Drug Administration's (FDA) issuance of a Request for Comments ("RFC") to provide input on the activities of the Opioid Policy Steering Committee (hereinafter, "Steering Committee"). 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 those efforts are appropriately balanced with the legitimate needs of the millions of patients living with pain. APhA emphasizes the importance of carefully considering and evaluating new policies in light of other federal, state and local efforts to prevent redundancy and unintended consequences. New policies should not create unnecessary burdens or compete with other work being done to effectively address the opioid epidemic.

APhA is generally supportive of FDA's efforts to enhance the risk-benefit framework and education related to opioids and believes each of these components are part of a multipronged approach to address use, abuse and misuse of opioid medications. APhA recommends FDA take a collaborative approach to complement and improve upon efforts already underway. APhA is committed to working with FDA, 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 while maintaining safe, accessible, and appropriate treatment options for patients with acute and chronic pain. We offer the following comments to further the impact of FDA's efforts.

I. Assessing Benefit and Risk in the Opioids Setting

APhA is supportive of FDA's efforts to reassess the risk-benefit framework used to evaluate opioids for needed updates or changes. In addition to misuse and abuse, APhA recommends other public health considerations and events linked to opioids should be considered, including

risk of fall, especially in the elderly population. For example, research has demonstrated certain older patients using opioids are more likely to suffer a fracture compared with patients who initiate non-steroidal anti-inflammatory drugs (NSAIDS).[1] Accordingly, APhA recommends FDA also consider falls in its benefit-risk framework and research other events and issues that may be linked to opioid use.

Additionally, as FDA evaluates the benefits and risks with opioids, the agency should better ascertain the effectiveness of different components of REMS programs generally. Currently, there is limited research regarding the effectiveness of the components of REMS programs, which was a mechanism created to mitigate risks associated with certain drug products. However, the degree of risk mitigation associated with each REMS program is not clear. APhA encourages research regarding the effectiveness of REMS program components.

II. Steps to Promote Proper Prescribing and Dispensing

1. *Should FDA consider adding a recommended duration of treatment for specific types of patient needs (e.g., for specific types of surgical procedures) to opioid analgesic product labeling? Or, should FDA work with prescriber groups that could, in turn, develop expert guidelines on proper prescribing by indication?*

APhA is not supportive of FDA recommending a duration of treatment for specific types of patient needs within opioid analgesic product labeling. As far as APhA is aware, there is limited research regarding a recommended duration of treatment covering variable patients and their conditions. For example, even for specific types of surgical procedures, research is inconsistent and may not account for other interventions, such as physical therapy or non-opioid medications.[2,3,4] In addition, APhA believes such standardized, generalized labeling could undermine or be inconsistent with practitioner judgment and efforts to individualize care. This is especially true given the fact payers often rely on drug labeling when making coverage decisions. Instead, APhA recommends FDA, along with other federal agencies, facilitate and support research regarding the optimal timeframe for short-term opioid use.

APhA is amenable to the idea of FDA working with prescriber groups, including pharmacists, to develop guidelines informed by best evidence on the proper prescribing of opioid products by indication. However, APhA strongly recommends any such guidelines need to contain statements regarding their application clinically, clearly articulating they are not to be used to create coverage policies or as a basis for thresholds in regulations and laws. Recently, several states and payers have implemented broad policies relying on thresholds noted in federal guidelines, ignoring other guideline language referencing clinical judgment. Should FDA decide to develop guidelines related to proper opioid prescribing, in addition to prescribers, APhA

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[1] Miller, M., Sturmer, R., Azrael, D., Levin, R. & Solomon, D.H. (2011). Opioid analgesics and the risk of fracture in older adults with arthritis, *Journal of the American Geriatric Society*, 59(3), DOI: 10.1111/j.1532-5415.2011.03318.x.

[2] *See* Hill, M. McMahon, M., Stucke, R. & Barth, R.J. (2017). Wide variation and excessive dosage of opioid prescriptions for common general surgical procedures, *Annals of Surgery*, 265(4), 709-714.

[3] *See also*, Gerbershagen, H.J., Aduckathil, S., van Wijck, A.J.M., Peelen, L.M. & Kalkman, J. (2013). Pain intensity on the first day after surgery: A prospective cohort study comparing 179 surgical procedures, *Pain Medicine*, 118, 934-944.

[4] *See also*, Devin, C.J. & McGirt, M.J. (2015). Best evidence in multimodal pain management in spine surgery and means of assessing postoperative pain and functional outcomes, *Journal of Clinical Neuroscience*, 22(6), 930-938.

strongly recommends including stakeholders representative of the care continuum, including those involved in pain and palliative care, and patients.

2. *If opioid product labeling contained recommended duration of treatment for certain common types of patient needs, how should this information be used by FDA, other state and Federal health agencies, providers, and other intermediaries, such as health plans and pharmacy benefit managers, as the basis for making sure that opioid drug dispensing more appropriately and consistently aligns with the type of patient need for which a prescription is being written?*

As noted above, APhA has concerns with FDA adding a recommended duration of treatment for different types of patient needs to opioid product labeling because it could restrict practitioner judgment and prevent individualized care. Including recommended duration of treatment in labeling could result in payers basing coverage decisions on listed durations and consequently, adding administrative burden for health care practitioners seeking to tailor care to patient needs as well as delays in treatment. Such a result is at odds with advancements in precision medicine and the desire to better tailor treatment to meet the variable needs of individual patients.

3. *Are there steps FDA should take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice?*

Pharmacists frequently dispense and package medications to patients in a manner which improves adherence and meets patients' needs. While APhA believes certain packaging can help improve safety, we have concerns certain packaging (e.g., locking vials) could result in additional costs for patients and pharmacies and have not been proven effective. Moreover, packaging intended to reduce risk of diversion is not appropriate for all patients and can actually increase harm to patients and their families. For example, a patient using a locking vial may decide to leave the vial open rather than attempt to open it for each use as they may forget the code or have motor difficulties. APhA recommends FDA consider real-world use of alternative packaging, like the pilot projects currently being conducted in Illinois, before implementing such policies.[5] In addition, if such packaging is required, APhA recommends the risks associated with different types of packaging be disclosed to patients and practitioners.

An area in which APhA and its members believe FDA can have an important and positive role is in the area of drug disposal. Our membership indicates patients can be confused by what constitutes appropriate disposal and the risks of disposal. As more disposal solutions are coming to market and suggested by health care practitioners, it is important messaging be consistent, simple and be evidence-based. APhA believes FDA can help develop and promote educational resources related to safe and effective disposal options that are easy for consumers to implement.

4. *Are there other steps that FDA should take to help promote the prescribing of treatment durations that are appropriately tailored to a clinical patient need?*

[5] *See* Ilinois State Senator Iris Y. Martinez, *Illinois to test locking devices for painkillers*, available at: http://www.senatoririsymartinez.com/news/23-news-releases/232-illinois-to-test-locking-devices-for-painkillers

APhA encourages FDA to support the inclusion of indications or diagnosis codes on prescriptions. Often, pharmacists will receive a prescription with little context regarding a patient's condition or circumstances. Pharmacists are the medication experts on care teams and receive more medication-related 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.

III. Requirements for Prescriber Education

1. *Are there circumstances under which FDA should require some form of mandatory education for health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations, understand how to identify the risk of abuse in individual patients, know how to get patients with a substance use disorder into treatment, and know how to prescribe treatment for—and properly manage—patients with substance use disorders, among other educational goals? Are there other steps FDA could take to educate health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations?*

As FDA considers new educational requirements, it is important they are not developed in a vacuum as providers are already subject to numerous federal, state and payer requirements. APhA recommends any required education to improve health care professionals' prescribing practices needs to be evidence-based. Furthermore, as with any new requirement, educational requirements should be evaluated post-implementation to determine if intended goals of the mandate are achieved and to assess any unintended consequences. APhA believes such evaluation allows for refinement or changes to better respond to patient and public health needs.

2. *How might FDA operationalize such a requirement if it were to pursue this policy goal? For example, should mandatory education apply to all prescribing health care professionals, or only a subset of prescribing health care professionals? If only a subset, how would FDA construct a framework that focuses mandatory education on only that subset—for example, by requiring mandatory education only for those writing prescriptions for longer durations as opposed to those for very short-term use?*

Should FDA require some form of mandatory education for health care professionals, we believe FDA should make clear that mandatory education policies are not intended to limit the type of providers eligible to prescribe opioids. In some states, pharmacists working under a collaborative practice agreement may prescribe opioids. Any mandatory educational requirement should not preclude health care professionals, such as pharmacists, from prescribing opioids in a manner consistent with state scope of practice laws. Additionally, because not all health care professionals work with patients who take opioids, health care professionals who do not work with patients who take opioids, such as nuclear pharmacists, should be exempt from opioid-related mandates.

3. *What steps should FDA take to make implementing such mandatory education efficient and more feasible? For example, should FDA work collaboratively with state public health agencies, state licensing boards, provider organizations, such as medical specialty societies and health plans, or with other stakeholders, such as pharmacy benefit managers, to*

integrate or avoid duplicating their educational programs or requirements? What other steps might FDA consider to make implementation less burdensome and more effective?

a. Education

Currently, many states, state licensing boards and employers require health care professionals complete opioid education as a condition of licensure or employment. As a result, a significant amount of education is already developed and used by health care practitioners. However, the content of such education varies and is often not evaluated for effectiveness or meant to complement other educational requirements or specific practitioner needs. APhA encourages FDA to work with states and potentially employers to consider harmonizing education to prevent duplicative requirements and conflicting content.

In addition, several professional associations develop and provide continuing education for health care professionals. Education offered by associations and other similar entities tends to reflect needs specific to the profession or specialty. Rather than FDA taking a one-size fits all approach to education, APhA encourages FDA to rely on education from professional associations and other like entities currently providing education rather than developing standalone education.

b. Verification

APhA is concerned that the burden of verifying a prescriber's fulfillment of an educational mandate could fall on the pharmacist, which would become more burdensome and complicated as the number of entities mandating opioid-related education increases. Requiring pharmacists to access multiple systems, as currently occurs for checking and reporting into prescription drug monitoring programs (PDMPs), is time-consuming and detracts from pharmacist-patient interactions and patient care. The pharmacist is also the likely health care professional to have to find a solution for a patient whose prescriber failed to satisfy the mandatory education requirement. Any method to verify prescriber education should be seamless and not become the responsibility of the dispensing pharmacist. Moreover, adequate mechanisms will need to be in place to assure that patients with legitimate pain needs are not penalized from receiving appropriate treatment in a timely manner due to new mandates, especially those not proven to be effective.

c. Implementation timeframe

APhA encourages FDA to carefully analyze the time necessary to implement a mandatory education policy. If an appropriate amount of time is not allotted for the implementation of new educational requirements, which would include communication to prescribers and an adequate time for training, patient care will be negatively impacted. Delays in prescriber education, verification, and renewal processes could result in unintended consequences at odds with the goal of the policy as well as further fragmenting patient care. Consequently, without a clear process and time for prescribers to comply, patient access to needed medication will be impeded, possibly forcing patients to switch between prescribers or be driven to illegal alternatives.

d. Variability of Prescribers and Practices

When considering any requirement for prescribers of opioids, it is important to remember there are a wide-variety of health care professionals who prescribe. While many view pharmacists strictly in a dispensing role, APhA notes that pharmacists may also prescribe opioids in certain states.[6] Consequently, APhA suggests FDA consider the impact and logistics of mandatory education for all the different types of prescribers of opioids, including pharmacists, before developing and implementing mandatory education.

IV. Additional Matters for Consideration

APhA appreciates the efforts of FDA and the Steering Committee to gather input for future policy considerations. While pharmacists play a crucial role in helping optimize safe medication use, their services are often not covered by payers, including Medicare. APhA encourages FDA to work with other federal agencies to implement policies that realize the value pharmacists can provide to patients and the health care system.

Lastly, APhA emphasizes its desire to work with the Steering Committee, helping to inform its members of the role pharmacists do and can play in curbing opioid abuse and misuse and preventing overdose. We encourage the Steering Committee to collaborate with APhA and other professional and patient associations as it considers new policies and approaches to address the opioid epidemic.

Thank you for the opportunity to provide comments in response to the Steering Committee's RFC. APhA believes it is imperative a proper balance be maintained between delivering appropriate pain management for the millions of patients with legitimate needs for opioids and taking steps to minimize and prevent opioid misuse and abuse. As FDA moves 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,

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

[6] *See* Centers for Disease Control and Prevention. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017.