Dec. 28, 2017

Kathleen Davies
Office of Medical Products and Tobacco
Food and Drug Administration
Bldg 1, Room 2310
10903 New Hampshire Ave.
Silver Spring, MD  20993

Re:  Opioid Policy Steering Committee; Request for Public Comment (Docket No. FDA-2017-N-5608)

Dear Ms. Davies,

The Healthcare Distribution Alliance (HDA) is pleased to provide input in response to the request for public comment for the Food and Drugs Administration’s (FDA) Opioid Policy Steering Committee (OPSC). HDA applauds the Administration’s focus on finding solutions to the opioid abuse epidemic, including its work across numerous departments and offices to provide assistance to those who need it most.

HDA represents primary pharmaceutical distributors, the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. HDA and its members work daily to provide value and achieve cost savings for our nation’s healthcare system. HDA previously was known as the Healthcare Distribution Management Association.

We offer these comments with the ongoing goal of contributing to solutions to reduce the abuse and misuse of controlled substances—including opioids—while also allowing prescribers and patients timely access to those important medicines in cases of legitimate medical need. As logistics companies who take seriously their responsibility to be part of the solution, primary pharmaceutical distributors have invested heavily in information technology systems to help better flag suspicious ordering patterns, have enhanced overall “know your customer” due diligence efforts to further prevent the abuse, misuse and potential diversion of controlled substances such as opioids, and continue to support efforts designed to improve coordination and communication with regulators and supply chain partners. HDA also supports additional
initiatives, described in our Practical Solutions to Address Opioid Abuse and Misuse,¹ that will enhance and improve the systemic response to addiction and the abuse of opioids.

We provide comments on two specific questions.

First, in section II, FDA asks:

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?

HDA supports FDA’s proposal to work with prescriber groups that would develop expert guidelines on proper prescribing by indication. We note that this approach has previously been supported by the American College of Emergency Physicians² and the American Society of Regional Anesthesia and Pain Medicine.³ We understand that some related efforts are already underway by prescriber groups.

In developing expert guidelines, prescriber groups can account for specifics of the practice, and can work in collaboration with state medical boards and other entities that govern the practice of medicine. As other commenters have pointed out, healthcare professionals do not practice in a “one size fits all” manner. While the Centers for Disease Control (CDC) have developed a necessary and useful Guideline for Prescribing Opioids for Chronic Pain, that guideline is intended for the primary care setting. Where that guideline uses vague language like “major surgery”—necessary because of its broad applicability—prescriber groups can delve deeper into details and can address both pharmacologic and nonpharmacologic treatments appropriate to specific situations.

Ideally, prescriber groups and their partners will develop plans to disseminate their newly developed guidelines and any additional educational materials. FDA’s assistance in dissemination may be useful. As the National Academies of Sciences, Engineering, and Medicine described, “Prescribing guidelines may be able to improve provider prescribing behavior but may be most effective when accompanied by provider education and other measures designed to facilitate implementation.”⁴ The sharing and uptake of such information still presents challenges: despite the attention to the opioid prescribing guideline issued by the

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CDC last year, not all prescribers are aware of it, according to the Final Report issued by the President’s Commission on Combating Drug Addiction and the Opioid Crisis.

Second, FDA asks in section IV:

2. Are there additional policy steps FDA should consider relating to the OPSC that are not identified in this notice?

HDA supports the National Academies report, Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use, including its thoughtful and considered recommendations for FDA action.

HDA also supports patient education. As the President’s Commission described in its Final Report this year, “Patients are often ill-informed about the risks of taking opioid analgesics and, therefore, are not able to balance the potential benefits of opioid analgesics with the associated risks.”5 HDA supports the Commission’s recommendation for a national prevention strategy focused on sharing “prevention messages specific to opioids, to include patient and family education on what opioids are, the hazards of opioids, safeguarding of prescription medications, and disposing of unused pills.”6

HDA also supports greater education of patients about their ability to request a “partial fill” of their opioid prescription. Partial fill provisions allow pharmacists to dispense part of the prescription on one day and, if the patient or prescriber asks, the remaining prescription in a few days. Partial fill provisions mitigate the likelihood that a patient would have more medication than he or she needs, but still allow patients to receive the entire amount if necessary. This also provides the pharmacist and patients with additional opportunities to interact, allowing the patient to ask any new questions and the pharmacist to provide advice and to detect signs of misuse.

Thank you again for the opportunity to provide input. We hope that our comments are useful to you, and stand ready to provide additional input or assistance as the OPSC’s work proceeds. We wish you every success moving forward.

Kind regards,

Ruth K. Miller
Senior Director, Regulatory Affairs

5 President’s Commission on Combating Drug Addiction and the Opioid Crisis, Final Report 49 (2017).
6 Id. at 46.