



September 30, 2016

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

**RE: FDA–2016–N–0584, Anesthetic and Analgesic Drug Products Advisory Committee, the Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee; Notice of Meeting**

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments on the use of prescription opioid analgesics for pediatric patients. We recognize that opioid use and misuse continues to be a public health crisis in the United States, which also extends to the pediatric population. The AANA makes the following comments regarding this topic:

- Parent / Caregiver education is an important safety component of opioid prescribing in the pediatric population.
- A multimodal approach to pain management should be considered as part of the patient-specific treatment plan and can lessen the need for opioid use.
- Pediatric pain management involves a multidisciplinary approach; therefore, education should extend to all members of the multidisciplinary team and be aligned with national guidelines.
- The FDA should continue to collaborate with SmartTots research to develop best practice for pediatric opioid administration and prescribing.

**Background of AANA and CRNAs**

The AANA is the professional association representing more than 50,000 Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists in the United States. More than 90 percent of the nation's nurse anesthetists are members of the AANA. CRNAs are advanced practice registered nurses who personally administer more than 40 million anesthetics to patients each year in the United States. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

**Parent / Caregiver education is an important safety component of opioid prescribing in the pediatric population.**

Patient-centered education, which includes parents and caregivers of pediatric patients, offers greater understanding and engagement in safe administration and prescribing of opioids. An understanding of the

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etiology of pain, treatment plans and goals, treatment options and alternatives, as well as consequence to non-adherence to the pain management plan supports the patient and caregivers with information to address pain and to improve safety. Clinicians should be cognizant of parents and caregivers who are non- or low-literate English speakers when providing information regarding the patient's treatment and at-home medication use.

Safe opioid prescribing practices include review of package/bottle instructions and providing printed medication information in an understandable, clear format, including explicit instructions for appropriate dosing and administration, particularly regarding opioid combination medications (e.g., instruct that separate acetaminophen dosage is not to be given when administering an opioid-acetaminophen combination medication). Parent and caregiver education should also include age- and condition-appropriate pain assessment of their children to identify pain intensity as well as a review of potential side effects and appropriate ways to address those side effects. Additionally, non-opioid pharmacologic and non-pharmacologic pain management modalities should be discussed to minimize the need and use of opioids.

When an opioid is appropriate, the prescription should be appropriate for the duration and type of pain. Prescribers should assess the duration of therapy when prescribing opioid medications to ensure that the prescribed amount is sufficient, but does not include an excessive amount of unneeded medication. To minimize the risk of children or adolescents gaining access to prescribed opioids, clear instructions should be provided for the proper disposal of any unused medications, as well as access to readily available and secure locations for safe disposal. At the time of medication dispensing, the parents or caregivers should be encouraged to address any additional concerns regarding medication administration or disposal with the pharmacist or the prescribing clinician.

**A multimodal approach to pain management should be considered as part of the patient-specific treatment plan and can lessen the need for opioid use.**

A multimodal, multidisciplinary approach, including the use of non-pharmacologic, behavioral, and pharmacologic approaches to pain management should be used when possible. The multidisciplinary team should involve pain specialists, such as CRNAs, who can provide a focused pain assessment and evaluation to develop a patient-specific pain management plan. When appropriate, the use of an enhanced recovery after surgery (ERAS) protocol, to include multimodal pain management, may reduce the child's stress response to surgery, minimize use of opioids, and accelerate the return to normal daily function.<sup>1,2</sup> For pediatric surgical pain, a preemptive approach to acute pain management, integrating regional anesthesia techniques as part of the analgesic bundle, may improve the child's postoperative acute pain experience.

**Pediatric pain management involves a multidisciplinary approach; therefore, education should extend to all members of the multidisciplinary team and be aligned with national guidelines.**

The AANA supports multidisciplinary provider education regarding appropriate, evidence-based administration and prescribing of opioid medications for the pediatric population as well as alternative non-pharmacologic and non-opioid pharmacologic modalities for pain management that minimize the use

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<sup>1</sup> Leeds IL, Boss EF, George JA, Strockbine V, Wick EC, Jelin EB. Preparing enhanced recovery after surgery for implementation in pediatric populations. *J Pediatr Surg*. Sep 5 2016.

<sup>2</sup> Shinnick JK, Short HL, Heiss KF, Santore MT, Blakely ML, Raval MV. Enhancing recovery in pediatric surgery: a review of the literature. *J Surg Res*. May 1 2016;202(1):165-176.

of opioids. A pediatric pain management team is often multidisciplinary, including parents or caregivers, child life specialists, and clinicians across numerous specialties, such as pediatrics, primary care, surgical specialties, and anesthesia. Opioids can be an effective element of a comprehensive plan to manage pain. Providers are educated to appropriately prescribe opioids for the pediatric patient, balancing the patient's right to pain management while working towards a reduction for the potential of opioid overdose or misuse.

Drug manufacturers should be urged to create pediatric-specific documents and materials as part of the FDA's Risk Evaluation and Mitigation Strategies (REMS) systems. Standardized pediatric materials would be beneficial to all clinicians who treat the pediatric population in providing consistent care.

The AANA also supports the continued research of safe and effective pediatric pain management and expansion of existing guidelines, such as the Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain* or the AANA [Chronic Pain Management Guidelines](#), to include pediatric-specific recommendations for pain management. The AANA welcomes the opportunity to collaborate and serve as a resource on this effort.

**The FDA should continue to collaborate with SmartTots research to develop best practice for pediatric opioid administration and prescribing.**

Pediatric pain research continues, particularly with the efforts of the SmartTots initiative, which is supported by the FDA and the International Anesthesia Research Society (IARS). AANA supports expanding funding and identification of new funding sources (e.g., industry partners) for continued pediatric acute and chronic pain management research.

We thank you for the opportunity to comment and further partner with the FDA on this important issue. Please do not hesitate to contact Lynn Reede, DNP, MBA, CRNA, FNAP, Senior Director, Professional Practice, at (847) 655-1136 or [lreede@ana.com](mailto:lreede@ana.com) if you have any questions or comments.

Sincerely,



Cheryl Nimmo, DNP, MSHSA, CRNA  
AANA President

cc: Wanda O. Wilson, PhD, MSN, CRNA, AANA Chief Executive Officer  
Lynn Reede, DNP, MBA, CRNA, FNAP, AANA Senior Director, Professional Practice