



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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December 21, 2017

Scott Gottlieb, MD
Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: FDA-2017-N-5608

Dear Dr. Gottlieb,

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Association of Orthopaedic Surgeons (AAOS) thanks the FDA for the opportunity to comment on its newly established Opioid Policy Steering Committee (OPSC).

The AAOS understands the United States has an epidemic of opioid drug use, misuse, and abuse. Curbing the number of inappropriate, non-therapeutic opioid prescriptions and the public's overall opioid consumption requires comprehensive reforms with input from all stakeholders. To be successful, stakeholders need to work together to increase research funding for alternative pain management techniques; improve prescription monitoring; and create more effective education programs for clinicians and patients.

Populations vary geographically, and, currently, the literature supports few generalizable pain management protocols for specific procedures and conditions. The AAOS supports standardized protocols, established at the practice level, with the guiding principle that providers prescribe the lowest effective dosage for the shortest duration, to control the number of prescriptions and potential misuse. As researchers and medical professional organizations determine which pain management methods are most appropriate and effective, variation in prescribing habits will decrease. Meanwhile, these practice-level protocols would set ranges for acceptable dosages and durations for various surgical and non-surgical conditions. The AAOS is concerned that national standards established arbitrarily and without the requisite evidence could limit inappropriately patients' access to necessary pain management.

The AAOS strongly believes that electronic prescribing of medications promotes patient safety. E-prescriptions for all opioids would help not only appropriate use and patient convenience, they would provide data in a format that could provide better surveillance of excessive, inappropriate, and non-therapeutic prescribing. To further promote appropriate prescribing, clinicians could consider two smaller prescriptions, with specific refill dates, rather than a single, large prescription. Many patients do not fill the second prescription, so this strategy would limit the number of pills in circulation and potential opioid diversion. Additionally, providers should

consider policies and protocols that limit or restrict opioids for preoperative and nonsurgical patients. Research has shown that patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.

The AAOS believes physicians' enhanced understanding of opioid analgesics and alternative, multimodal pain management techniques would lead to better patient outcomes. Specialty-specific education is an effective means of controlling variance in prescribing habits and will enhance physician and caregiver awareness of the risks and appropriateness of opioid medications. Education should include clinician-patient communication strategies, which help patient education and aid shared decision-making.

It is important to be mindful of the fact that provider requirements vary from state to state and equally important to recognize that different medical specialties require education tailored to meet the needs of their respective patients. A one-size-fits-all approach poses significant challenges and may have unintended consequences. With that, AAOS believes that medical professional organizations are best positioned to provide relevant and meaningful education to its members and patients.

The AAOS thanks the FDA for the opportunity to provide comments to the Opioid Policy Steering Committee and looks forward to working together so that we can end the national opioid abuse epidemic. Should you have questions, please do not hesitate to contact AAOS's Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.

Sincerely,

A handwritten signature in black ink that reads "William J. Maloney". The signature is written in a cursive style and is positioned above a large, stylized, abstract scribble that appears to be a flourish or a large, loopy signature element.

William J. Maloney, MD
President, American Association of Orthopaedic Surgeons

cc: David A. Halsey, MD, AAOS First Vice-President
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