



January 16, 2018

Leslie Kux, Associate Commissioner for Policy  
Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Associate Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the [request for comments and public hearing](#) titled, “Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation” published by the Food and Drug Administration (FDA) in the December 13, 2017 *Federal Register*.

We appreciate that the FDA seeks to receive stakeholder input on how FDA might, under its Risk Evaluation and Mitigation Strategy authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics. In our July 10, 2017 [letter](#) to the FDA, the AAFP acknowledged the intertwined public health issues of chronic pain management and the risks of opioid misuse. We recognize that high levels of misuse and addiction persist with devastating consequences despite the annual decreases in the number of opioids prescribed in the United States since 2010.

In spite of advances in evidence and understanding of its pathophysiology, chronic pain continues to burden patients in a medical system that is not designed to care for them effectively. Opioids have been used in the treatment of pain for centuries, despite limited evidence and knowledge about their long-term benefits, but there is a growing body of evidence regarding their risks. As a result of limited science, external pressures, physician behavior, and pharmacologic development, we have seen the dramatic consequences of opioid misuse, diversion, dependence, and overprescribing.

Family physicians are the most visited specialty—especially in underserved areas. Family physicians conduct approximately one in five of all office visits in the United States. This represents more than 192 million visits annually. Family physicians therefore find themselves at the crux of the issue, balancing care for patients with chronic pain and the challenges of managing the appropriate use of opioids, while always mindful of their misuse and abuse. In the face of opioid misuse, family physicians have a unique opportunity to be part of the solution. Both pain management and dependence therapy require patient-centered, compassionate care as the foundation of treatment. These are attributes that family physicians bring to their relationships with patients.

[www.aafp.org](http://www.aafp.org)

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The AAFP strives to protect the health of the public, and we are keenly aware of the critical and devastating problem of prescription drug abuse. At the same time, we need to address the ongoing public health requirement to provide adequate pain management. While our currently fragmented health care system is not well-prepared to address these interrelated issues, the specialty of family medicine is well-suited for this task. The AAFP is actively engaged in the national discussion on pain management and opioid misuse. Committed to ensuring that our specialty remains part of the solution to these public health crises, the AAFP challenges itself and its members at the physician, practice, community, education, and advocacy levels to address the needs of a population struggling with chronic pain and/or opioid dependence.

The AAFP supports effective state prescription drug monitoring programs (PDMP) that facilitate the interstate exchange of registry information as called for under the *National All Schedules Prescription Electronic Reporting Act*. We advocate for physicians to use their state PDMP before prescribing any potentially abused pharmaceutical product. However, the success of such efforts depends on state reporting systems that are accessible, timely, interoperable, and comprehensive. We must work together to make prescription drug monitoring effective for the sake of the public's health. In April 2017, the AAFP Board of Directors agreed to support an interoperable secure national database to support a robust National Prescription Drug Monitoring Program. Until such time as the United States has a National PDMP, the AAFP and our 54 chapters will continue working to encourage the use of state PDMPs and bring localized and state specific education to our members and their care teams.

Family physicians are deeply committed to fine-tuning their ability to prescribe opioids appropriately and effectively. AAFP members reported completing well more than 141,000 continuing medical education (CME) credits on this topic in 2016. To help address opioid abuse and addiction, the AAFP recognizes the need for evidence-based physician education to ensure safe and effective use of extended-release and long-acting (ER/LA) opioids as well as short acting opioids. The AAFP continues to believe educating physicians is an important tool, but to be impactful, the education must be designed to address needs and gaps of the learners. "One size fits all" education is not optimal.

Recognizing the current epidemic, late in 2016 the AAFP updated our "Chronic Pain Management and Opioid Misuse: A Public Health Concern" [position paper](#) to better equip members to combat the opioid abuse crisis while continuing to treat chronic pain. Additionally, the position paper directs members to the AAFP's new opioid and pain management toolkit. The AAFP encourages practices to use the toolkit to evaluate current policies regarding pain management and opioid prescribing.

The AAFP opposes limiting patient access to any physician-prescribed pharmaceutical without cause, as well as any actions that limit physicians' ability to prescribe these products based on the physician's medical specialty.

The FDA should focus less on an individualized clinician approach that ignores team based care, and more on promoting patients as stakeholders in their own care via shared decision making and collaborative physician-patient management plans. These are fundamental concepts that recognize the importance of primary care, and specifically family medicine, in dealing with the opioid epidemic.

**About Family Medicine**

Family physicians are dedicated to treating the whole person. These residency-trained, family medicine specialists are trained to deliver comprehensive primary care. They treat babies with ear infections, adolescents with depression, adults with hypertension, and seniors with multiple chronic illnesses. With a focus on prevention, primary care, and overall care coordination, they treat illnesses early and, when necessary, refer their patients to the right specialist and advocate for their care. Family physicians take 66 million more office visits than the next largest medical specialty. More Americans depend on family physicians than on any other medical specialty.

We appreciate the opportunity to provide these comments. Please contact Teresa Baker, Senior Government Relations Representative, at 202-232-9033 or [tbaker@aafp.org](mailto:tbaker@aafp.org) with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John Meigs, Jr.", with a stylized flourish at the end that includes the letters "MS".

John Meigs, Jr., MD, FAFAP  
Board Chair