July 10, 2017

Anna K. Abram
Deputy Commissioner for Policy, Planning Legislation, and Analysis
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA– 2017–N–1094 and Docket No. FDA– 2017–D–2497

Dear Deputy Commissioner Abram:

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 titled, "Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics—Exploring the Path Forward" as published by the U.S. Food and Drug Administration (FDA) in the April 18, 2017 *Federal Register*. I also write in response to the related request for comments on the FDA Blueprint for Prescriber Education for Extended Release and Long-Acting Opioid Analgesics (Blueprint) made available in the May 10, 2017 *Federal Register*.

The intertwined public health issues of chronic pain management and the risks of opioid misuse continue to receive national attention. The AAFP thanks the FDA for the opportunity to provide oral testimony to the FDA during related public workshops in May. We are cautiously optimistic that the amount of opioids prescribed in the United States has decreased each year since peaking in 2010. However we also fully recognize that high levels of misuse and addiction persist.

Despite 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 overprescribing, misuse, diversion, and dependence.

Family physicians 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.. 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. 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 readily bring to their relationships with patients.

AAFP strives to protect the health of the public, and we are deeply 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 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, and interoperable. We must work together to make these systems effective for the sake of the public health. The AAFP and our 54 chapters will continue working to bring localized and state specific education to our members and their care teams.

Family physicians already 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. Since then, the AAFP has participated in several related initiatives, including efforts by the White House, HHS, and other federal agencies to solve the opioid crisis, in addition to working with the AMA Task Force to Reduce Opioid Abuse.

In order 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. However, we maintain that mandating CME for individual prescribers is not the solution for this public health crisis. Therefore, we oppose policies that would require mandatory education of family physicians as a condition for prescribing opioids.

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. AAFP encourages practices to use the toolkit to evaluate current policies regarding pain management and opioid prescribing.

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. Requiring all physicians or “prescribers” in this case to complete the same education, regardless of whether a relevant performance gap in this area exists, would be a disservice to that physician and their patients since it will result in unnecessary time spent away

from patient care. Mandated CME also impacts a family physician's ability to complete the most relevant education focused on specific needs and gaps.

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.

Regarding the FDA Blueprint for Prescriber Education for Extended Release and Long-Acting Opioid Analgesics (Blueprint), we are concerned that it is overly proscriptive. Instead, the AAFP recommends that FDA add education on shared-decision making and patient-centric counseling to its recommendations. 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. These are currently missing within the Blueprint.

Under "diagnostic studies" on page 2, we remind the FDA that there are many instances of acute pain that do not have a clear precipitating event. In addition, diagnostic imaging is not always clinically required, especially if imaging does not assist the primary care physician in diagnosis or treatment decisions. Unnecessary imaging is also costly for the entire health system. Please refer to the AAFP's Choosing Wisely recommendation against imaging for low back pain without red flags.

On the 3rd page, within the general principles of pharmacologic analgesic therapy section, we recommend the FDA add a statement that physicians be knowledgeable about side effects and risks.

Within the dosing section on the 7th page, the FDA should acknowledge that it is impossible for physicians to fully monitor patients in the outpatient setting for extended periods of time. Instead of the language used, we recommend the FDA encourage physicians to educate patients regarding the signs, symptoms and risks of respiratory depression.

Also on the 7th page, within the review adverse events discussion, we suggest the FDA fully cite evidence based medical literature regarding screening for endocrine function.

Finally, on the 8th page within the Opioid rotation section, we again remind the FDA that physicians, due to limited time and the need to see other patients, are not able to monitor without pause for respiratory depression.

We appreciate the opportunity to provide these nominations and recommendations, and are available for your questions at your convenience. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

Wanda D. Filer, MD

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Board Chair