



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

July 3, 2013

Leslie Kux, Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

RE: Docket No. FDA–2013–N–0502, Standardization and Evaluation of Risk Evaluation and Mitigation Strategies, Public Meeting

Dear Assistant Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 110,600 family physicians and medical students nationwide, I write in response to the notice of public meeting and [request for comments](#) titled “Standardization and Evaluation of Risk Evaluation and Mitigation Strategies” as published in the May 22, 2013 *Federal Register*.

The AAFP appreciates that the FDA is holding a two-day meeting to discuss the issues and challenges associated with the standardization and assessment of risk evaluation and mitigation strategies (REMS) for drug and biological products. Pain management and opioid abuse are serious public health concerns and we are pleased that the AAFP Medical Director for Continuing Medical Education (CME), Ann Karty, M.D., FFAFP, will represent the AAFP as a registered speaker at the public meeting on July 25 and 26.

Overall, the AAFP shares with the FDA a commitment to making sure that patients continue to have access to appropriate pain medications and that all opioid products are used safely and effectively. The AAFP remains dedicated to finding solutions to the crisis of pain management care and opioid abuse and as such we released a [position paper](#) titled “Pain Management and Opioid Abuse: A Public Health Concern” which contains several key recommendations. We are pleased that the FDA and the White House Office of National Drug Control Policy continues to address this ongoing public health crisis resulting in the latest [report](#) titled “Epidemic: Responding to America's Prescription Drug Abuse Crisis.”

Family physicians and other primary care clinicians play a vital role in effective pain management, including prescribing opioid analgesics. We remain concerned with any policies that would create additional prescribing barriers for primary care physicians since

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their professional judgment and clinical experience determine whether there is legitimate need for pain relief.

To educate family physicians about this growing epidemic, the AAFP offers dedicated CME since the foundation of CME is a family physician striving to provide the best possible patient care. As a national CME accreditor, the AAFP continues to be actively involved in conversations with the FDA, the REMS program committee, other credit systems and CME provider organizations and we are pleased to receive grant funding to support CME that addresses the educational goals identified in an FDA CME/CE [blueprint](#), which details the core messages to be covered in educational offerings for prescribers of ER/LA opioids.

The AAFP is developing live, online and self-study CME activities that align with the educational goals set forth by this FDA blueprint so that our CME offerings are in compliance with relevant accreditation guidelines to ensure validity. The FDA currently requires ER/LA opioid analgesic manufacturers to make this CME available for prescribers, which the AAFP supports. However, the AAFP would not support any mandates that require physicians to complete the CME. We believe voluntary participation will help to address the growing problem of prescription drug abuse and misuse.

In addition to these CME opportunities, the AAFP will soon offer our members a webinar titled "Chronic Pain and Safe Use of Opioids." This chronic pain course will focus on educating family physicians about chronic, nonmalignant pain and encouraging them to talk with patients about past or present risk factors. The curriculum will use outcomes data gleaned from the "Mission: Pain Management -- The Efficient First Visit" session held during the 2012 AAFP Scientific Assembly.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Glen Stream MD". The signature is written in a cursive, slightly slanted style.

Glen Stream, MD, MBI, FAAFP
Board Chair