



Michael D. Maves, MD, MBA, Executive Vice President, CEO

July 8, 2010

Kristine T. Khuc  
c/o Melanie Whelan  
Food and Drug Administration  
10903 New Hampshire Avenue  
Building 51, Room 6100  
Silver Spring, MD 20993-0002

**RE: Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee  
and the Drug Safety and Risk Management Advisory Committee  
[Docket No. FDA-2010-N-0001]**

Dear Ms. Khuc:

The American Medical Association (AMA) is pleased to present its views on the FDA's proposed Risk Evaluation and Mitigation Strategy (REMS) for Long-Acting and Extended-Release Opioids. The AMA's previous recommendations to the FDA on this topic are in substantial agreement with the FDA's proposal for a class REMS directed to long-acting and extended release opioids. The AMA commends the FDA for taking a thoughtful and deliberate approach in addressing the diverse public health issues associated with the use of these clinically important products, and in recommending an approach that is more likely to avoid unintended consequences in patients with chronic pain or terminal illness. As we previously recommended, the AMA also appreciates the FDA's wisdom in soliciting public comment on the proposed REMS and submitting it to the Agency's Advisory Committee(s) for review.

The AMA has consistently acknowledged the need for better training on pain management and substance use disorders and supported the use of positive incentives (including CME) for completion of supplemental training in a voluntary manner as opposed to mandatory certification. Similarly, the FDA's proposal notes that although companies are to provide such additional training, it is not mandatory (at this time) for physicians to complete training in order to continue to prescribe long-acting and extended release Schedule II opioids. The AMA is willing to provide assistance in fostering acceptance, and participation in, this approach among our member physicians. The AMA previously supported the concept that additional educational requirements for opioid REMS should include the input of practicing physicians. We urge that the "independent third party" tasked with developing the educational component referred to in the FDA proposal be directed to accommodate this approach.

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Like the FDA, the AMA acknowledges the need for better information on appropriate patient selection, awareness of factors contributing to unintentional overdoses, and efforts to reduce diversion and non-medical use of opioid medications. The AMA also supports the need for appropriate patient counseling and adherence monitoring, but opposes (as mandatory) other practices that are already considered as necessary in certain patients including the use of patient-physician agreements, specific monitoring schedules, or urine tests. The AMA, therefore, supports the FDA proposal requiring sponsors to provide FDA-approved patient education sheets for prescribers to use in their interactions with patients in order to promote safe use and offer advice on the proper storage and disposal of opioids. The AMA agrees with the FDA that other mandatory elements directed to patient care are not deemed to be necessary.

Importantly, the AMA agrees with the FDA's decision against establishing registries for patients, or for real time verification of prescriber training at the pharmacy level. The AMA would strongly oppose any effort to reverse, or modify, these features of the proposal.

The AMA, and many others, have previously noted the overriding importance of having the appropriate metrics in place to evaluate not only potential harms to patients from opioid medications, but also potential harms to patients with chronic pain or terminal illness. Substantial concerns exist that such patients may suffer inadequate pain management or access to care if an opioid REMS, which substantially increases burdens on patients or prescribers, is implemented. The FDA proposal acknowledges the need to develop better metrics, and the fact that the Agency has initiated collaboration with a number of its Federal partners to accomplish this goal is encouraging.

Finally, the AMA has previously noted that in order to effectively address the range of public health issues presented by the clinical use and misuse of opioids, a coordinated effort is needed among various federal and state agencies along with significant participation by the health care community. We support the FDA's stated intention to partner with other Federal agencies and appropriate stakeholders in the private sector under the Agency's Safe Use Initiative to implement programs that more broadly address the public health problems related to the misuse and abuse of prescription opioids.

The AMA appreciates the opportunity to comment on this important issue and would be pleased to cooperate in helping to engage the physician community in being responsive to this proposal, if and when it is implemented.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA