

## ACTION ALERT

### The FDA Threatens to Remove Long Acting Opioids Unless the Benefits of these Medications Outweigh the Risks FDA Requests

#### *Public Participation in the Development of a REMS*

#### The Issue

On February 6, 2009, the FDA sent letters to 24 manufacturers of opioid analgesics (both long and short-acting) to let them know that they would be required to develop a comprehensive Risk Evaluation and Mitigation Strategies (REMS) plans. According to the FDA, the purpose of the REMS would be to ensure that the benefits of the drugs continue to outweigh the risks (misuse, abuse and accidental overdose). [Click here to view the entire document.](#)

#### Request for Public Participation

The Food and Drug Administration (FDA) is seeking input on the development of Risk Evaluation and REMS for opioids. The FDA is accepting written or electronically submitted [public comments](#) on opioid REMS until June 30, 2009, and they are particularly interested in comments on the following issues:

- The type of certification that should be required of prescribers and dispensers of opioids, including how this certification should be administered
- The type of patient education on opioids that should be required, including whether or not to mandate the use of prescriber-patient agreements
- Other REMS elements besides health care provider certification and patient education that would support the safe use of opioids
- How restrictive a REMS system for opioids should be
- What types of controls, if any, should be placed on distributors that provide opioids to pharmacies and health care facilities
- Whether or not existing systems can be used to implement a REMS for opioids
- The obstacles that need to be addressed in order to develop a single, shared REMS system for drug innovators and generic manufacturers
- The metrics that should be used to assess the success of REMS

#### How You Can Help

The Academy requests that you, as a member of our organization (or as an individual clinician who treats people with pain), send a letter or an email to the FDA offering your opinions, comments, and/or recommendations regarding efforts to develop and implement Risk Evaluation and Mitigation Strategies (REMS) for certain opioid medications. (See FDA Announcement below for submission information).

Your participation will help guarantee that the legitimate medical uses of opioid analgesics will be given consideration equal to or greater than that of the criminal misuse of these valuable medications. Now is the time to make your voices heard!.

**Submit written comments to:**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

[Click here to submit electronic comments](#)

All comments should be identified with the docket number [Docket No. FDA-2009-N-0143]

## The Academy's Participation and Recommendations

For several months Executive Director, Lennie Duensing, and Board of Directors member (and a member of the Minnesota Board of Medical Practice), Al Anderson, MD, have been participating in the Pain Care Forum's Opioid Risk Evaluation and Mitigation Strategies (REMS) Task Force and education subcommittee to develop and provide recommendations to the FDA on various elements of the REMS. They have also been attending FDA stakeholders meetings. At (at least) three stakeholders' meetings, one that was attended by Lennie Duensing and Al Anderson, the FDA threatened to remove long acting opioids from the market unless an acceptable REMS was submitted (paraphrase).

On May 28, Lennie Duensing spoke on behalf of the Academy at the FDA's public meeting (along with 77 other stakeholders) and urged the FDA to:

**1) Acknowledge that chronic pain as one of our nation's greatest public health problems** (and one that is certain to worsen as our population ages and people live longer). Today, more than 33 million Americans—men, women, and children live with serious pain that has lasted one year or more. Very often, this pain goes untreated, undertreated, or improperly treated. And this is particularly true for underserved populations (i.e., the elderly, the poor, and people of color).

**2) Take every measure possible to ensure that people who live with life-robbing pain have the right to have access to the safest and most effective treatments available to them.** Keep in mind that long acting and extended release opioid formulations were used by nearly 4 million patients in the United States in 2007, and that their right to pain management should not be forfeited due to the criminal misuse of these valuable medications

**3) Apply principles of sound science and rigorous research to demonstrate evidence of the effectiveness of elements of the REMS.** REMS are designed to reduce the risk of abuse, misuse, or diversion, and enough time must be allowed to gather existing data perform pilot studies in specific geographic areas of the country where opioid abuse is prevalent.

**4) Not include patient registries as a part of the REMS.** There is no evidence to suggest that a patient registry will diminish abuse or misuse of these medications. Evidence does exist, however, showing that such an approach would stigmatize patients and impose significant burdens on all parties, resulting in diminished prescribing and inadequate pain management. Enhancements to the existing and growing state Prescription Monitoring Programs infrastructure would be a better option to consider for achieving the REMS goals.

**5) Include the entire class of opioid medications in the REMS plan.** Any attempt to regulate only a portion of the opioid class of medications will drive prescribers, users, and misusers of these medications to the other, less stringently, regulated members of this class of medications. In general, this will not diminish abuse or misuse and will very likely result in some patients not getting the medications that are most appropriate for their needs. 3) Tie REMS prescriber and dispenser education to the DEA registration process to maximize participation. No program works without broad participation or compliance. Connecting the prescriber and dispenser educational offerings with a known DEA licensing process provides a meaningful opportunity to engage the greatest number of providers in the vital educational component of the REMS.

**6) Develop REMS education programs with extensive expert input.** The REMS should provide a comprehensive core curriculum that builds on trainings, offerings and approaches already proven to work. The curriculum should be offered through a variety of mechanisms to have the broadest reach and accessibility, including online, print, and/or live session offerings.

**WE URGE YOU TO TAKE ACTION IMMEDIATELY. IN ADDITION TO SUBMITTING COMMENTS TO THE FDA, YOU MAY ALSO WANT TO SEND YOUR LETTERS TO CONGRESSIONAL MEMBERS**