

**Advice from May 3-4, 2016 Drug  
Safety and Risk Management  
(DSaRM) and Anesthetic and  
Analgesic Drug products (AADPAC)  
Advisory Committee**

January 25, 2017

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# Background-May 2016 AC

- The 36-month REMS Assessment Report for ER/LA Opioid Analgesic REMS was received July 2015.
- Included data on all assessment items from phased assessment plan:
  - Available training programs
  - Number of training participants
  - Patient and provider survey results
  - Drug Utilization data
  - CE Audit data
  - Surveillance of events of interest

## Background-May 2016 AC

- Purpose of meeting was to present findings from the REMS assessment and seek advice from the Committees on whether the REMS:
  - is meetings its goals
  - assures safe use
  - is not unduly burdensome on patient access and minimizes burden to the healthcare delivery system
  - should be modified; possible modifications include
    - expansion of the scope of the blueprint (e.g., include immediate-release opioids and pain management principles)

# FDA Conclusions on REMS Assessment

- Difficult to determine impact of REMS program in light of many other efforts
- Many limitations of survey and surveillance data
- Methods to determine if prescribing behavior of trained prescribers is different from untrained should be further developed

# Committee Discussion

- Expectations for reach of voluntary program
- Effectiveness of REMS assessment data sources and methodologies
- Impact of ER/LA Opioid Analgesic REMS on patient access to opioid analgesics
- Whether the REMS is meeting its stated goal
- Whether the scope of the FDA blueprint is sufficient
- Whether the Medication Guide and Patient Counseling Document are sufficient
- Whether a REMS for the immediate release opioid analgesics should be required
- Whether prescriber education should be required to prescribe an opioid analgesic

# Voting Question

- Considering all available information, which one of the following options do you recommend FDA pursue regarding the ER/LA Opioid Analgesics REMS?
  - a. Continue without modifications
  - b. Eliminate the REMS
  - c. Modify the REMS

## Committee Vote

- Continue the REMS without changes
  - 0
- Eliminate the REMS
  - 0
- Modify the REMS
  - 30

## Highlights of rationale

*“Just to second that [support by others for addition of immediate-release opioids to REMS], I hope the answer is a unanimous yes. And I think the focus is not on any one high-risk product. It’s on the chronic use of opiates for chronic pain and the various safety risks and concerns. And that really is the focus and not the product.”*

James Floyd, MD, MS, Adjunct Assistant Professor of Epidemiology, Dept of Medicine, University of Washington

## Highlights of rationale

*“Providing every provider with some modicum of understanding of pain in our society would be a very good thing. And at the same time, you can provide the information that those providers who prescribe would need to do that effectively, and therefore actually move the ball on this issue; because, if you divorce the drug-specific issue from the thing that's driving it, which is pain in this country, you're doomed to failure, in my opinion.”*

Chester “Trip” Buckenmaier, MD, Program Director, Defense and Veteran’s Center for Integrative Pain Management, Professor of Anesthesiology, Uniformed Services University

## Highlights of rationale

*“I think the expectation of the reach of this educational program, for what some people have been calling a national emergency, is that we involve every person we can. I've listened to the folks in the public part of this, and I agree that it's really a team effort and everybody should be involved. “*

Raeford E. Brown, Jr., MD, FAAP, Professor of Anesthesiology and Pediatrics, College of Medicine University of Kentucky

## Highlights of rationale

*“I think there is fairly overwhelming, not complete, but overwhelming agreements that this should be a mandatory educational system. I think everybody is doubting how much of an impact it has, but it also is, I think, very clear that everybody agrees that proper prescribing practices should be available and should be given to every opiate prescriber.”*

Almut Winterstein, RPh, PhD, FISPE (Chairperson), Professor and Interim Chair Pharmaceutical Outcomes and Policy College of Pharmacy, University of Florida Gainesville

# Advisory Committee Advice

- Expand REMS requirements to include immediate-release (IR) opioid analgesics
- Expand the FDA blueprint to incorporate pain management and education messages for other healthcare professionals involved in the management of patients with pain
- Require that education be mandatory, though options other than a REMS should be explored

