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AAPM Recommendations to the FDA Regarding REMS: ER/LA Opioids

The American Academy of Pain Medicine (AAPM) appreciates this opportunity to provide public comment as a major stakeholder to the joint meeting of the Drug Safety & Risk Management Advisory Committee and the Anesthetic & Analgesic Drug Products Advisory Committee on May 3-4, 2016. AAPM is an interdisciplinary society of pain medicine that is committed to ensuring the safety, efficacy, and cost-effectiveness of patient care through evidence-based care, patient-centered research, public and professional education, and science-based policy.

Risk Evaluation and Mitigation Strategies with Elements to Assure Safe Use (REMS with ETASU) for extended release / long acting (ER / LA) opioids have been a positive step in physician education, and while no program can entirely “assure safe use,” the FDA Blueprint for Prescriber Education contains much of the critical information necessary to enhance safer use of this class of medications. AAPM believes that the current REMS for ER / LA opioids is not burdensome to the healthcare delivery system (including medical providers), nor does it limit patient access to these medications. We would, however, like to offer the following suggestions in order to enhance the effectiveness of the program.

1. We highly recommend the development of a REMS program for immediate release / short acting (IR / SA) opioids with development of a concomitant Blueprint for Prescriber Education. Educational highlights should underscore the appropriateness of this class of medication for the treatment of acute pain, while balancing the risk / benefit to each individual patient, and address how to appropriately transition therapy to non-opioids, or other adjunctive pain relieving strategies.
2. We highly recommend that education be mandatory for the prescription of methadone for chronic pain due the unique characteristics and highly variable pharmacokinetics of this drug. Overdose deaths from methadone are increasing at an alarming rate.
3. We recommend the FDA consider making the opioid REMS programs mandatory for all prescribers, and incorporate assessment tools to document prescriber proficiency with safe prescription practices. AAPM does not, however, favor linking mandatory education to DEA licensure. State-level regulation of provider qualifications may be a better avenue to explore.

4. It would be beneficial to strongly emphasize major safety concerns regarding the use of ER / LA opioids within the blueprint for CME/CE providers to ensure that higher-risk aspects of their use are highlighted (e.g., concomitant use with benzodiazepines). The blueprint provides a wealth of information, with the unintended consequence that critical aspects of safety may be overlooked in the myriad of information provided.
5. We suggest recommendations be added to the blueprint regarding education on the role of prescribing naloxone along with ER / LA opioids.
6. We call for funding research to determine the impact of REMS and opioid education on: (a) provider prescribing, knowledge, competencies, etc.; and (b) the impact of these programs upon patients' access to appropriate opioid therapy.

We have purposefully kept our comments brief in an effort to provide clarity concerning these recommendations. Other potential comments, such as the potential value to explore individual pharmacogenetics as a determinant of opioids' risk / benefit ratio, may have merit but are not among the above "top-tier" recommendations at this time. If further documentation is desired regarding the detailed rationale for any of these suggestions, AAPM would be glad to provide this. Thank you for this opportunity to positively impact the care and safety of our patients.