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American Pain Society (APS) Policy Related to FDA REMS Decision, July 23rd, 2010

Background

In response to a request by Congress that FDA address rising morbidity and mortality associated with prescription opioid misuse, in June 2010 the FDA proposed a risk mitigation and evaluation strategy (REMs) for long acting and controlled release opioids. On July 23rd, 2010, the FDA's Advisory Committee rejected the proposed REMS as not going far enough to address the problems. APS supported the REMS proposed by the FDA as a good first step towards improving the safe and effective prescribing of opioids for pain. However, we respect the concerns of the Advisory Committee that voluntary training of prescribing clinicians alone is not sufficient to assure safe prescribing, nor is it sufficient to address the broader societal problem of non-medical use of prescription opioids. And we strongly concur that a more comprehensive approach is needed to address this serious public health problem.

APS Policies related to Non-Medical Use of Opioids and Opioid REMS

As a community of scientists and clinicians of diverse professions and specialties, APS encourages multidimensional care of patients with chronic pain that addresses the full spectrum of biopsychosocial needs of the individual. Opioid therapy may, or may not, be required as a component of effective care of chronic pain for individual patients.

APS policies related to non-medical use of prescription opioids and opioid REMS support:

- A class wide REMS that covers all opioids, not just long-acting and controlled-release opioids
- More intensive education in pain medicine and addiction medicine in core healthcare professional training with routine assessment of opioid prescribing competence on professional board examinations.
- Demonstration of requisite knowledge for competent prescribing of controlled substances, assessed and documented by an appropriate professional organization (or organizations), as a prerequisite to obtaining or renewing DEA registration
- A public awareness campaign that targets awareness of:
 - The benefits of opioids when used properly
 - The harmful and lethal potential of opioids when misused

- Appropriate storage of opioids in locked containers
 - Information on safe disposal of opioids
- Expansion and improvement of Prescription Monitoring Programs to :
 - Include all 50 states
 - Assure seamless inter-operability between states
 - Provide real time access to information for prescribing clinicians and pharmacists
- The implementation of take-back and/or buy-back programs aimed at facilitating removal of no longer needed prescription opioids
- Outcomes monitoring of all REMS and other interventions intended to reduce non medical use of prescription drug to assure that goals are met and negative unintended consequences identified and eliminated.
- Expanded NIH, CDC, DOD and other governmental agency support for research on effectiveness, side effects, benefits and complications of opioid therapy.

Specific Responses to the REMS Advisory Committee

Although the proposed REMS released by FDA in June, 2010 did not fully meet APS's policies, we believe that these proposals were actionable initial public safeguards that fell within the FDA's limited jurisdiction. Importantly, once in place, the scope of these initial strategies could be expanded expeditiously - either directly or indirectly. For example, although the FDA's initial proposals did not include immediate-release, short-acting opioids in the proposed REMS, APS believes that most clinicians who use long-acting or controlled-release opioids also prescribe immediate-release, short-acting opioids and thus prescribers trained in the principles of safe prescribing of long-acting and controlled-release opioids are likely to improve prescribing of other opioids as well.

Additionally many of the needed strategies suggested by the advisory committee and consistent with APS policies are outside the scope of the FDA's authority in creating a REMS. For example:

- The FDA has no jurisdiction over undergraduate professional training, over the evolution or funding of Prescription Monitoring Programs, or over how research funding is directed by other Federal agencies.

- Federal legislation is likely needed to require education or demonstration of competence in association with DEA registration and to develop effective drug take-back programs.

On the other hand, APS does not support the creation of new opioid patient registries suggested by some members of the Advisory Committee because:

- Based on information provided by Federal agencies, 95% of U.S. residents are currently covered by existing or legislatively authorized Prescription Monitoring Programs. Thirty six states have active PMPs, an additional 8 have PMP legislation in place and others appear poised to follow.
- It seems unlikely that implementation of an additional set of opioid patient registries would be more timely than expansion of PMPs and improvement of existing PMPs
- In the context of well functioning universal PMPs, an opioid registry would be redundant and add unnecessary burden to the healthcare system.

Finally, APS urges caution in developing mandatory prescriber training requirements for opioid prescribing – making sure to avoid prescribers opting out of ever treating patients in pain with opioids. APS believes that, ideally, education leading to competency in opioid prescribing should be integrated into undergraduate and graduate professional education and should be demonstrated as part of routine professional board and licensing exams. However, in the interim we support accelerated legislation leading to a requirement for education or demonstration of competence to competently prescribe opioids (administered by a professional organization or organizations) as a pre-requisite for DEA registration. Such a prerequisite would likely be the most expedient way to assure appropriate universal prescriber education without interruption of needed patient care. If other interim requirements for mandatory education are enacted, APS will support only forward-thinking educational mechanisms that do not interrupt patient care nor deter physicians from becoming credentialed to provide such care.