CHICAGO, Sept. 17, 2013 /PRNewswire-USNewswire/ -- The physicians of the American Academy of Pain Medicine (AAPM) hailed long-awaited labeling changes and other steps taken by the U.S. Food and Drug Administration (FDA) last week to enhance safety in the prescribing of extended-release and long-acting (ER/LA) opioids. AAPM further supported the Agency's decision to deny portions of a citizen petition seeking dosage and treatment duration limits that would have applied to every patient regardless of individual circumstance. The Academy had previously argued that the proposed limits were arbitrary, lacked scientific substantiation, and could lull prescribers into solely focusing on dose, which could have led to ignoring additional risk factors.

The FDA considered thousands of comments and pieces of scientific literature to reach its recommendations, which were announced last week. Seeking today to provide perspective on what the FDA decisions mean for patient care, AAPM leaders praised the agency's careful, judicious review of the evidence and its move toward advocating individualized therapy.

"These were good moves for people who suffer the most intractable, severe pain and who find alternatives to opioids ineffective," said Lynn R. Webster, MD, president of AAPM. "It is important for us to put the FDA's actions in context and to make sure the clinical implications are understood. Incomplete or inaccurate reporting on what the agency did could influence a doctor's medical decisions, putting patients at risk."

One important development was adding a prominent boxed warning that babies born to mothers on opioids may experience opioid dependency and exhibit withdrawal symptoms.

The FDA further announced new requirements for holders of ER/LA applications to conduct long-term studies to assess risks of misuse, abuse, hyperalgesia (increased pain sensitivity), addiction, and overdose, and suggested that industry players work together to do so. The FDA wrote that it had found no "adequate and well controlled" studies beyond 12 weeks. "Everyone agrees -- or should -- that 'Support long-term studies' should be the rallying cry," Webster said.

The label indication will now change from "moderate-to-severe pain" to "severe enough" to warrant ER/LA opioids. AAPM supports the change as appropriate, believing it will encourage

more judicious prescribing, which should benefit patient safety and -- ultimately -- public safety.

"To say the pain must be severe enough to indicate treatment, encourages evaluation of the individual patient on important factors beyond what a pain scale score can show," Webster said. "That distinction, although emphasized by the FDA, was lost in the reporting by some media outlets."

Furthermore, the FDA now says these medications may be used only when alternative therapies would be inadequate, which fits with AAPM's tenet that long-term opioid therapy should be limited to patients whose benefit from it outweighs potential harm. It should be noted, however, that FDA did not require patients to fail alternative therapies first, regardless of the severity of pain or the type of pain involved. Instead, a clinician must assess each patient's risk, and then monitor therapy closely.

The FDA also did not impose a daily dose limit of 100 mg morphine equivalents, nor did the FDA limit treatment duration to 90 days, citing lack of scientific basis for those proposals.

Areas that need further attention, according to AAPM leaders, include better information on the role played in opioid-related overdoses by methadone and by frequently found co-intoxicants, such as benzodiazepines and antidepressants. Furthermore, the FDA did not specifically address the impacts of long-term opioids on hormonal and immune systems in its call for post-approval research.

Full information on the labeling changes and the responses to two citizen petitions, including the one from PROP, be read here at the Drug Safety page of the FDA website.

About AAPM

The American Academy of Pain Medicine is the premiere 2,400-member medical association for pain physicians and their treatment teams. Now in its 30th year of service, the Academy's mission is to optimize the health of patients in pain and eliminate it as a major public health problem by advancing the practice and specialty of pain medicine through education, training,

advocacy and research.

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