



**FOR IMMEDIATE RELEASE**

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### **Massachusetts Pain Initiative Statement on Zohydro ER**

Boston, MA - MassPI is opposed to Massachusetts' recent move to ban Zohydro ER and is concerned that the needs of thousands of Massachusetts residents who depend on opioid medications, including hydrocodone, were not discussed or considered in Massachusetts' actions. The only legitimate purpose for this medication is to help people living or dying with pain from serious, debilitating and in some cases life-threatening conditions yet few, if any news reports have discussed this fact.

A survey conducted by MassPI and reported in the *Boston Globe*, found that one in four adults in Massachusetts suffers from serious, persistent pain that interferes with their daily life and ability to work. Uncontrolled pain can devastate a person's quality of life, affecting all aspects of daily functioning including sleep, work, social activities and relationships. While opioid pain medications do not help everyone living with pain, the fact is that many require them, often in combination with other treatment modalities, to function on a daily basis and have any quality of life. When prescribed and properly administered to target populations with pain severe enough to require these medications, the incidence of abuse and addiction is extremely low.

We are concerned that much of what has been said about Zohydro ER is simply not accurate. This medication is not stronger than any medication on the market. There are many extended release/long acting (ER/LA) medications as strong or stronger than Zohydro ER. Only one ER/LA opioid currently on the market has abuse deterrent properties. While helpful in deterring some cases of abuse, this technology does not prevent oral abuse, the most common form of abuse, nor overdose in people who take too much or combine it with other licit or illicit drugs or alcohol.

What is true is that this medication fills an important need for the treatment of those living with severe chronic pain. It is well known that individuals respond differently to different medications and what works for one individual's pain may not work for another's. Also, many individuals have side effects with one type and medication and not with others. Hydrocodone combination medications have been safely used by millions of Americans to manage pain for years. As a result, they are the most frequently prescribed medications in the US. However, hydrocodone has never before been on the market as a single entity without the acetaminophen or ibuprofen. Many individuals cannot take acetaminophen, especially in high doses because of liver toxicity. The same is true for ibuprofen in high doses as it can have dangerous gastrointestinal, cardiac and renal toxicity. Zohydro ER is the first and only single-entity hydrocodone available product and as such would be an important option for pain sufferers who may not tolerate the addition of acetaminophen or ibuprofen or other opioids on the market.

The US Food and Drug Administration (FDA) is the federal agency charged with evaluating all medications in the US for safety and effectiveness. FDA scientists spend years carefully evaluating the scientific data on new medications balancing risks and benefits. After lengthy evaluation, the FDA concluded that the benefits of this medication for people living with pain severe enough to require daily, around the clock treatment outweighed the risks including the potential for abuse, misuse, addiction and overdose.

FDA has also gone to extraordinary lengths to mitigate the risks of this medication for abuse. As a part of the newly enhanced ER/LA Opioid labeling, Zohydro ER has a new, more restrictive indication in its labeling. It also has more warnings regarding the potential for abuse and addiction and the need for prescribers to be extremely cautious in prescribing the medication and monitoring and following up with patients. Zohydro ER is also part of the class-wide ER/LA Opioid Analgesic Risk Evaluation and Mitigation Strategy or REMS. The drug's manufacturer is required to conduct post-market studies to assess the risks of misuse, abuse, addiction, overdose, and death associated with long-term use of the product once on the market. The REMS also requires that a Medication Guide be given to

patients with each prescription filled and that the drug sponsor provide training to all who prescribe ER/LA opioids including information on how to recognize evidence of and potential for opioid misuse, abuse, and addiction.

Careful consideration of medical and scientific evidence rather than media hype and political considerations should govern access to medications that are critical for enabling a large portion of pain sufferers to be productive members in our society. Further, restricting access to medications for people with pain will do little to address the problem of preventing, identifying, and treating individuals with addiction disorders. By restricting medications for people with pain, those who are predisposed to the disease of addiction will likely turn to other medications or illicit substances like heroin. Research has shown that the increase in heroin use has been fueled in part, by OxyContin's move to an abuse deterrent only formulation. What this really demonstrates is that banning legitimate pain medications will not solve the misuse, abuse and addiction problems. People with addiction disorders need more resources for treatment of the disease of addiction, coordinated follow-up and continuing support. Currently, facilities for addiction treatment are difficult to find.

The unintended consequences of banning legitimate FDA approved pain medications will leave millions of Americans suffering in pain from conditions like cancer, diabetic neuropathy, sickle cell disease, complex regional pain syndrome, severe back pain, arthritis, phantom limb pain, trigeminal neuralgia, combat injuries, recovery and rehab following joint replacement surgery and many others paying a terrible price.

The Massachusetts Pain Initiative (MassPI) is a statewide, non-profit organization dedicated to ending needless suffering from pain and to improving the quality of life for all people affected by pain.