

State Attorneys General

A Communication from the Chief Legal Officers of the Following States and Territories:

Florida * Georgia * Illinois * Indiana
Kentucky * Maine

March 25, 2014

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

Dear Secretary Sebelius,

We write to you out of alarm over the U.S. Food and Drug Administration's recent approval of the new high-dose opioid painkiller Zohydro ER. We ask that you exercise your leadership in protecting the health and safety of our citizens and overturn this disastrous decision.

Our nation is confronting a growing prescription drug abuse epidemic. In 2011, prescription drugs were blamed for the deaths of 718 Hoosiers, a nearly 10 percent increase from 2010. That same year, in Kentucky, over 1000 people died of prescription pill overdoses. In 2010, there were more than seven Floridians dying a day due to prescription drug overdoses. As Attorneys General, we have prosecuted violators and continually engaged our citizens to help stop this epidemic. This balanced attack, combined with the efforts of the Drug Enforcement Administration, has undoubtedly saved many lives by preventing prescription drug overdoses.

We were pleased when the FDA made the correct decision in reclassifying hydrocodone as a Schedule II drug. Unfortunately, that important reclassification decision is inconsistent with the approval of Zohydro ER which is a painkiller that is 5 to 10 times more potent than currently available hydrocodone products.

It has been reported that Zohydro ER can be prescribed in pills ranging from 10 milligrams to as high as 50 milligrams. This is a substantial departure from current hydrocodone products that range from 5 to 10 milligrams. What is even more troubling is the fact that Zohydro ER will not contain any abuse-deterrent properties, thus allowing addicts to more easily crush, snort and inject this powerful drug. The FDA's own advisory committee recognized these risks and voted 11-2 against approval of Zohydro ER.

In December, we were part of a bipartisan group of 29 attorneys general who wrote to FDA Commissioner Dr. Margaret Hamburg warning that the approval of Zohydro ER "has the potential to exacerbate our nation's prescription drug abuse epidemic." Senators, Congressman, consumer groups, healthcare professionals and treatment providers have also sent letters urging the FDA not to release this dangerous drug. These demands, from all areas of expertise, cannot be ignored.

Given the potentially grave outcomes from the release of Zohydro ER, it is imperative that you act as soon as possible to keep this drug off the market until abuse-deterrent technologies and other safe guards have been implemented. Thank you for your consideration and we look forward to your assistance in ending out nation's prescription drug abuse epidemic.

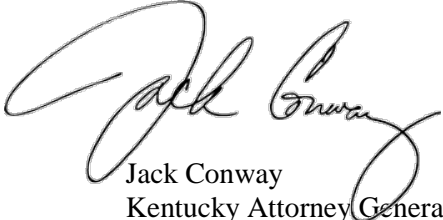
Regards,



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