State Attorneys General

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

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December 10, 2013

Margaret Hamburg, M.D. Commissioner of Food and Drugs U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Dr. Hamburg:

We write to you out of concern regarding your agency's recent approval of a new high-dose narcotic painkiller. We believe your approval of Zohydro ER has the potential to exacerbate our nation's prescription drug abuse epidemic because this drug will be the first hydrocodone-only opioid narcotic that is reportedly five to ten times more potent than traditional hydrocodone products, and it has no abuse-deterrent properties.

State Attorneys General do not want a repeat of the recent past when potent prescription painkilling drugs entered the market without abuse-deterrent qualities and without clear guidance on how they were to be prescribed. This created an environment whereby our nation witnessed a vicious cycle of overzealous pharmaceutical sales, doctors over-prescribing the narcotics, and patients tampering with these drugs, ultimately resulting in a nationwide prescription drug epidemic claiming thousands of lives.

We hope that the FDA either reconsiders its approval of Zohydro ER, or sets a rigorous timeline for Zohydro ER to be reformulated to be abuse-deterrent while working with other federal agencies to impose restrictions on how Zohydro ER can be marketed and prescribed.

Law enforcement officers, public health workers, and substance abuse treatment providers are just now beginning to stem the tide of prescription drug addiction. We do not want to see their dedicated work undone. Thank you for your consideration and we look forward to your response.

Sincerely,

Dr. Margaret Hamburg, Commissioner December 10, 2013 Page 2

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