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ATTORNEY GENERAL

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March 17, 2014

Hon. Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius,

I strongly urge you to overturn the Federal Drug Administration's recent approval of Zohydro Extended Release (Zohydro ER). As Attorney General of the State of New York, I have been extremely concerned about the deadly toll that abuse of prescription pain medications, particularly opioids, has taken on New Yorkers and on all Americans across the country.

Zohydro ER has been dubbed by some as "heroin in a pill" and is one of the most dangerous opioids on the market. More troubling, the pill lacks abuse-deterrent properties that prevent addicts and abusers from crushing, chewing, injecting, or snorting the drug. We cannot ignore the powerful lessons learned from the massive and unparalleled increase in drug abuse resulting from "crushable" OxyContin and other prescription opioids. It is simply irresponsible to manufacture these without abuse-deterrent formulas. It is incredible that Zohydro ER lacks these common-sense safeguards and repeats the mistakes of the past.

My office has urged the FDA to ensure that addictive opioids are sold with abuse-deterrent properties, including tamper-proof and crush-resistance formulas. Under New York State's Controlled Substances Act, hydrocodone is considered a Schedule II controlled substance. This reclassification of hydrocodone combination medications as Schedule II controlled substances was the first in a series of reforms undertaken in the State of New York to bring these dangerous drugs under tighter control.

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New York State has been a leader in innovative ways to addressing the prescription abuse crisis. Our historic Internet System for Tracking Over Prescribing Act (I-STOP) legislation, signed into law on August 27, 2012, made New York the first state in the nation to mandate eventual universal e-prescribing. This legislation has been credited with helping reduce prescription drug abuse by, among other things, addressing the problems of doctor shopping and the use of stolen or falsified prescriptions. With the help of the medical community, the State of New York has made substantial progress in the control of opioid drug abuse.

Please help all of us working to make our country safer and override the FDA's approval of Zohydro ER. This drug should not be prescribed or administered without adequate safety precautions. The release of Zohydro ER will exacerbate our state's prescription drug addiction problem and the use of illegal drugs that is connected with this problem.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Schneiderman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Eric T. Schneiderman