United States Senate
WASHINGTON, DC 20510

December 6, 2013

Margaret Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We are writing to express concern regarding the Food and Drug Administration (FDA) approval of Zohydro Extended Release (ER), a powerful, opioid drug product on October 25, 2013 (NDA 202880). This approval was given despite opposition of the FDA's own Anesthetic and Analgesic Drug Products Advisory Committee, which voted 11-2 against allowing Zohydro ER to advance in the approval process.

The minutes of the Advisory Committee make clear, "*Although the committee agreed that the Applicant met the Agency standards for efficacy and safety, the majority of the committee did not support the approval of this application. The committee agreed that standards for opioid product approval should be raised in light of the current public health concerns of abuse and misuse. The committee stated that the FDA should not approve ER/LA opioids without tamper-resistant or abuse-deterrent formulations, and that additional risk mitigation features should be adopted to strengthen the current ER/LA Opioid Analgesic REMS.*"

The rate of prescription pain medication misuse and death by unintentional opioid poisoning (overdose) has increased steadily across the nation. In New York, opioid overdose deaths have increased 65 percent since 2005. West Virginia opioid sales increased 125% between 2001 and 2011, with the state leading the nation in fatalities as a result of drug overdose. Nationally, 23.5 million individuals have used hydrocodone for non-medical purposes. According to the New York City Department of Health and Mental Hygiene, the introduction of abuse-deterrent technologies to oxycodone, another prescription opioid that has been subject to abuse, was responsible for reducing abuse and misuse of oxycodone drugs by 50 percent. Given the severity of the prescription drug epidemic, it is irresponsible for FDA to approve a single entity, hydrocodone bitartrate product that does not contain tamper resistant technology. This will only contribute to the rising toll of addiction and death.

On January 25, 2013, the FDA's own Drug Safety and Risk Management Advisory Committee voted 19-10 to reclassify hydrocodone. Subsequently, the FDA announced on October 24, 2013, their recommendation to reschedule the addictive drug from a Schedule III to a Schedule II opioid. The recommendation made by the FDA exhibits their awareness to the addictive nature of hydrocodone and the danger it causes to those who abuse the drug.

We ask that you explain the reason FDA ignored the recommendations of the Advisory Committee. Further, we ask that FDA work with Zogenix Inc., the manufacturer of Zohydro ER, to rapidly incorporate tamper resistant and abuse deterrent technologies into all commercially available forms of hydrocodone that they manufacture.

Sincerely,

Kirsten E. Gillibrand
United States Senator

Joe Manchin III
United States Senator

Dianne Feinstein
United States Senator

Amy Klobuchar
United States Senator