

# United States Senate

WASHINGTON, DC 20510

April 11, 2014

Commissioner Margaret Hamburg, M.D.  
The Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I write to express my concern about the Food and Drug Administration's October 2013 approval of Zohydro ER (hydrocodone bitartrate). The FDA approved this potent narcotic despite its own advisory panel's warnings that Zohydro lacked any deterrent against abuse and that it would "be associated with higher levels of abuse than hydrocodone combination products."

As you know, prescription narcotic drugs are the number one cause of overdose deaths in the United States. In 2011, the Centers for Disease Control (CDC) reported that over 22,000 Americans died of prescription drug related overdoses. Among these prescriptions, narcotic prescriptions killed more Americans than benzodiazepines, anti-depressants, and other sedatives combined.

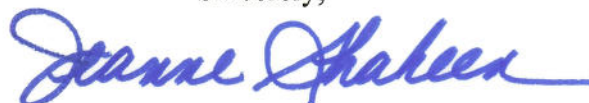
In 2011, the New Hampshire Center for Excellence, a public-private initiative of the New Hampshire Bureau of Drug and Alcohol Services and the New Hampshire Charitable Foundation, reported that there were 200 prescription drug related overdose deaths. Eighty percent of these overdose deaths were related to opioid pain relievers.

I am concerned that Zohydro will contribute to the ongoing epidemic of opioid drug abuse and overdose. In a recent decision, citing overdose risks, the FDA withdrew approval for products containing higher doses of acetaminophen. Similarly, I believe that there is a public health risk from Zohydro and ask that you review the approval of doses of Zohydro greater than any existing available dose for hydrocodone containing compounds. Further, if Zohydro is brought to market, I ask that you require a detailed post-market surveillance program that closely monitors and documents all cases of Zohydro abuse and overdose.

I do not believe we need to add to our existing problems, but rather, we need to appropriately monitor the currently available narcotic prescriptions, provide treatment for individuals suffering from addiction, and help law enforcement prosecute those who illegally procure and sell opioid prescription drugs.

I urge you to address the safety concerns surrounding Zohydro ER and to take the appropriate action to limit any potential abuse.

Sincerely,



Jeanne Shaheen  
United States Senator