Congress of the United States
Washington, DC 20515

November 22, 2013

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

Dear Secretary Sebelius:

We are writing to express our grave concern regarding the recent decision by the U. S. Food and Drug Administration (FDA) to approve the high-dose narcotic painkiller Zohydro ER, a Schedule II controlled substance under the Controlled Substances Act. The FDA approved this potentially harmful, hydrocodone-only drug without an abuse deterrent formula, despite a November 2012 internal FDA memo warning of the drug's high likelihood for abuse, and after the FDA's own advisory board in December 2012 voted 11-2 against approval, citing concerns over the potential for addiction.

This approval is extremely troubling and runs counter to recent, positive FDA announcements relative to the regulation of opioids. We support the FDA efforts to reclassify hydrocodone combination products such as Lortab and Vicodin to a more restrictive Schedule II drug and the updated labeling requirements for all extended release/long acting (ER/LA) opioid analgesics, but view this approval as a giant step backward.

Substance abuse is exacting a toll on America. The Centers for Disease Control and Prevention reported that there were 38,329 drug overdose deaths nationwide in 2010 and that prescription drugs were involved in nearly 60 percent of those deaths. The report also details that, consistent with previous years, opioid drugs, which include OxyContin and Vicodin, contributed to 3 out of 4 medication overdose deaths. In addition the National Institutes of Drug Abuse estimates the total overall cost of substance abuse in the United States, including lost productivity and health and crime-related costs, exceeds $600 billion annually. On many levels we simply cannot afford to move yet another highly addictive opioid into the mainstream and potentially onto Main Street.

Our concern does not suggest an indifference to the needs of severe chronic pain sufferers and we appreciate the difficulty that the FDA faces in balancing those concerns with reducing the proliferation of highly addictive opioids. However, instructive labeling and restrictive classifications will simply not prevent Zohydro from ending up in the hands of people for whom it was not prescribed.

The Milwaukee Journal-Sentinel reported on October 28, 2013, that Zogenix, the manufacturer of Zohydro, is working on a tamper resistant formulation of the drug and are committed to advancing the program as rapidly as possible. Given that the FDA is moving in the direction of stricter opioid controls, and that its own advisory board recommended against approval of Zohydro, we believe it would be prudent of the FDA to reconsider this approval until such time that the appropriate safety and abuse deterrent protections are in place.

Sincerely,

STEPHEN F. LYNCH
Member of Congress

HAROLD ROGERS
Member of Congress

NICK J. RAHALL
Member of Congress

WILLIAM R. KEATING
Member of Congress

VERN BUCHANAN
Member of Congress

JOHN F. TIERNEY
Member of Congress

MICHAEL E. CAPUANO
Member of Congress

JAMES P. McGOVERN
Member of Congress

cc. Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration