

Congress of the United States
Washington, DC 20515

December 17, 2015

The Honorable Stephen Ostroff
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff:

We write to express our concerns regarding the Food and Drug Administration's decision to approve the opioid prescription painkiller OxyContin for use by children as young as 11 years old.


Our country is suffering from a serious epidemic of opioid addiction and abuse. According to the Centers for Disease Control, 44 people die every day as a result of a prescription opioid overdose in the United States.

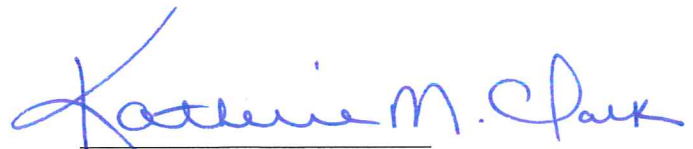
We understand that FDA's goal was to give doctors better guidelines on how to use OxyContin safely in pediatric patients. However, we believe that the flawed methodology used to arrive at this decision, as well as FDA's actual guidance, may actually encourage the expanded use of opioids among a population who are at an even greater risk of addiction.

As other federal agencies, including the Centers for Disease Control, Department of Health and Human Services, Office of National Drug Control Policy, and the Substance Abuse and Mental Health Services Administration work to combat this growing epidemic, we find it startling that FDA took this action without the benefit of review and input from an Advisory Committee. And, most egregiously, that FDA relied solely on an evaluation conducted by the pharmaceutical company who stands to benefit from the sale of this drug; a private company that only a few years ago pleaded guilty to falsely marketing the drug in a way that played down its addictive properties.

We strongly urge you to reconsider the decision to approve OxyContin for use by children and instead allow an Advisory Committee to gather public input and expert testimony before making an official recommendation.

Sincerely,


Niki Tsongas
Member of Congress


Katherine Clark
Member of Congress



Debbie Dingell
Member of Congress



Tim Ryan
Member of Congress



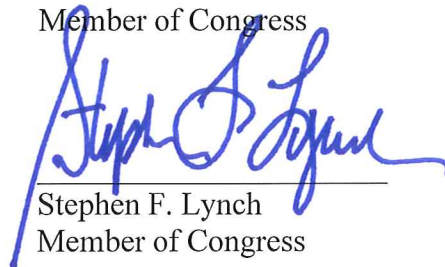
Harold Rogers
Member of Congress



Frank C. Guinta
Member of Congress



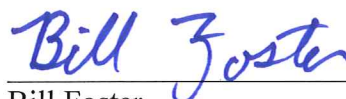
Michael E. Capuano
Member of Congress



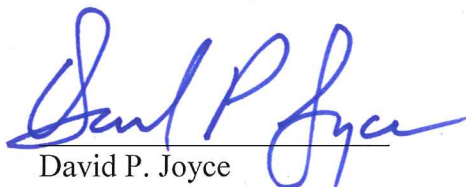
Stephen F. Lynch
Member of Congress



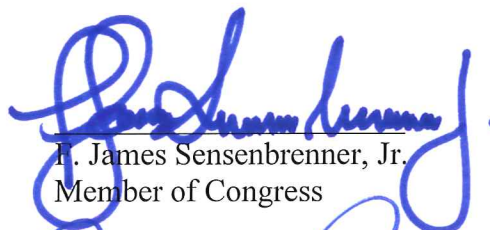
Marcy Kaptur
Member of Congress



Bill Foster
Member of Congress



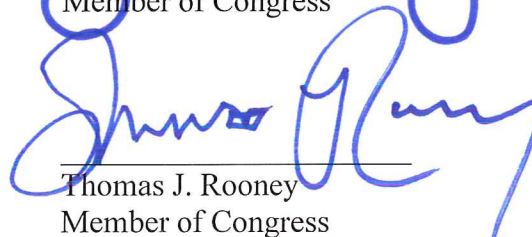
David P. Joyce
Member of Congress



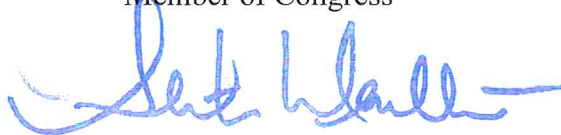
F. James Sensenbrenner, Jr.
Member of Congress



Robert J. Dold
Member of Congress



Thomas J. Rooney
Member of Congress



Seth Moulton
Member of Congress